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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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1997 ALL AGREEMENT STATES MEETING

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RADIOLOGY HEALTH BRANCH

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SATURDAY,

OCTOBER 18, 1997

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LOS ANGELES, CALIFORNIA

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The All Agreement States Meeting convened at the Westin Los Angeles Airport Hotel, 5400 West Century Boulevard, Los Angeles, California, at 8:30 a.m., Francis X. Cameron, Facilitator.

PRESENT:

FRANCIS X. CAMERON

DR. DONALD COOL

CATHY HANEY

CAROL S. MARCUS, Ph.D., M.D.

MARVIN B. COHEN, M.D.

JOHN R. WHITE, M.D.

ALSO PRESENT:

CATHY ALLEN

ED BAILEY

MAX BATAVIA

MIKE BRODERICK

MARILYN C. WEXLER, M.S., DABR

ROBERT E. CARRETTA, M.D., FACNP

STEVE COLLINS

VICK COOPER

PAUL EASTVOLD

JOHN ERIKSON

DON FLATER

ROLAND FLETCHER

TERRY C. FRAZEE

STEPHEN GAVITT

AUBREY GODWIN

BOB GOFF

BOB HALLOSAY

BRIAN HEARTY

MIKE HENRY

TOM HILL

JAY HYLAND

VICKIE JEFFS

JOE KLINGER

STUART LEVIN

ALSO PRESENT (CONT.):

STAN MARSHALL

RUTH McBURNEY

JAMES L. McNEES, CHP

MIKE MOBLEY

AARON PADGETT

RAY PARIS

BILL PASSETTI

TOM PATTERSON

DAVID C. PRICE, M.D.

BOB QUILLEN

RICHARD RATLIFFE

ALICE ROGERS

LYNN ROY

BILL SINCLAIR

DAVID SNELLINGS

ROGER SUPPES

DIANE TAFFT

JARED THOMPSON

DAVID WALTER

KEN WANGLER

RONNIE WASCOM

KEN WEAVER

KIRK WHATLEY

A-G-E-N-D-A

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Dr. Don Cool, NMSS, NRC	
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P-R-O-C-E-E-D-I-N-G-S

(8:30 a.m.)

FACILITATOR CAMERON: Well, good morning, everybody. Today we're going to focus. Hopefully we're going to focus shortly. We're going to focus on the NRC's rulemaking initiative on the regulations concerning the medical use of byproduct material.

Don Cool from the NRC's staff and Cathy Haney, who is over here for those of you who haven't met her, of Don's staff are going to provide you with some background information on the rulemaking issues.

It's important for the NRC to get the agreement state perspective on these issues, specifically on a number of options that the NRC staff has formulated on the rulemaking issues. So the heavy lifting is going to be done by all of you around the table, and we're going to have some help from some people in the audience on that score.

Now, I want to welcome all of the members of the public I think primarily or exclusively from the medical community in California to the meeting. And later on we'll be asking everybody to just introduce themselves. But I thank them for being with us today.

As you know, this portion of your meeting, the agreement state meeting, is open to the public because of

the nature of the issue that we're discussing, this particular rulemaking initiative. And, in addition to our discussion around the table, I plan to go out to the audience for public comments. And I know that that comment will inform our discussions today.

However, I also want to emphasize that the primary purpose of the discussion today is to get agreement state perspectives on the issues. So the bulk of the discussion is going to take place around the table.

As Don will mention, we do have two public workshops planned that are going to focus on public comment on these issues. Now, unfortunately one's in Chicago. I don't mean to insult the people from Illinois. I didn't mean it to sound like that.

(Laughter.)

FACILITATOR CAMERON: I should have said, unfortunately, one is in Philadelphia. We have a Midwest meeting, and we have an Eastern meeting. So this is the only time that the representatives from the medical community in California can give us their perspective on the issues. So we're going to take a little bit of leeway and let them do that today.

Now I would ask everybody, but particularly members of the public just because of the shorter time periods perhaps for public comment, to be concise and to

try to keep your comments to the issue that's on the table.

We do want to get through all of the discussion issues that Don has. And we have a short amount of time. So I may at some point have to limit comments. I don't think that we'll get into that, but we do have to sort of march through these.

Our schedule, we're beginning at 8:30. We have until 2:15 today, perhaps a little bit longer. I don't know what the state of the agreement state business meeting is. But, at any rate, we have until approximately 2:15.

We have a break for lunch at noon and a 10:15 break for coffee. They're going to keep the coffee place open over here. They usually close it before that, I understand, but they're going to keep it open today.

What I'd like to do now is to just give you an overview, for everybody, about how we're going to go through the issues. Don Cool is going to sort of give a background about how we got here and talk about one of the over-arching issues for this whole rulemaking issue, which is the issue of risk and the phrase that is written on the sole of every foot of NRC staffers, "risk-informed, performance-based." So Don is going to talk about that

issue. We'll have some discussion on it. We'll go out to the public.

Next we're going to talk about the NRC policy statements, a 1979 policy statement. I think that then we're going to go to a number of cross-cutting issues. We'll go have discussion after each of these issues, including the policy statement.

The first one is Radiation Safety Committee. The second issue is a quality management program. The third one is the training and experience issue.

We're going to break for lunch. And we're going to come back and talk about the threshold for reportable events and patient notification and get into any sort of process issues; for example, agreement state flexibility.

And I think we're going to hear a lot of things about the California medical program today. So that reminds me of that phrase, "We didn't come here to bury Bailey but to praise him." But don't let this go to your head.

(Laughter.)

FACILITATOR CAMERON: Okay. Let's go to the audience for just a brief introduction of your name and affiliation. And please speak into the mikes. We had the mike frequencies turned down a little bit. So you really

need to talk into the microphone. I'm going to see how far this can get, but I think we'll start right with Dr. Marcus.

DR. MARCUS: Good morning. I'm Carol Marcus, a nuclear medicine physician from Harvard-UCLA Medical Center.

DR. COHEN: Hi. I'm Marvin Cohen, a physician, Chief of Nuclear Medicine at the VA Medical Center, Zepulvida just out here in the San Fernando Valley. However, I need a disclaimer. I do not speak for the Veteran's Administration or any other government entity.

DR. WHITE: My name is John White. I'm a Board-certified nuclear medicine physician practicing exclusive nuclear medicine in the private setting at Little Company of Mary Hospital in Torrance, just south of the airport about 15 miles.

MR. FRAZEE: I'm Terry Frazee, State of Washington.

MR. PATTERSON: I'm Tom Patterson, State of Louisiana.

MS. ALLEN: Cathy Allen, State of Illinois.

MR. HENRY: Mike Henry for Louisiana.

MR. WEAVER: Ken Weaver, Colorado Public Health.

DR. CARRETTA: Bob Carretta. I'm a nuclear medicine physician in Sacramento, California.

DR. PRICE: I'm David Price, also a nuclear medicine physician here at UCSF in San Francisco, California.

MR. KLINGER: Joe Klinger, State of Illinois.

MR. ENGLAND: Steve England, also with the State of Illinois.

MR. TATE: Arthur Tate, State of Texas.

MR. GORDON: Craig Gordon, NRC.

MS. HOWARD: Marsha Howard, State of Ohio.

MR. WALTER: David Walter, State of Alabama.

FACILITATOR CAMERON: Marsha and David are on the NRC working group with NRC staff that have developed the basic options. So we'd like to acknowledge that.

MR. WRIGHT: Bill Wright, Arizona.

MR. BONN: I'm Don Bonn, California Department of Health.

DR. WEXLER: Marilyn Wexler, a medical physicist, Los Angeles.

MR. HORNER: Jack Horner, NRC.

MS. McBURNEY: Ruth McBurney, State of Texas.

MR. GAVITT: Steve Gavitt, New York State Department of Health.

MR. EASTVOLD: Paul Eastvold, City of Illinois.

MR. OMO: Razor Omo, State of California.

MR. WOODRUFF: Richard Woodruff, NRC.

MS. HANEY: Cathy Haney, NRC.

MR. McNEES: Jim McNees, State of Alabama.

FACILITATOR CAMERON: Okay. Let's do the back row here as well as the two. We're just introducing ourselves.

MS. ROY: Lynn Roy, California.

FACILITATOR CAMERON: Great.

MR. THOMPSON: Jared Thompson, Arkansas.

FACILITATOR CAMERON: And, Lynn, I think you're also with the medical community; right?

MS. ROY: Yes. I didn't know how we were introducing ourselves.

FACILITATOR CAMERON: California was good.

MR. SCOTT: Philip Scott, California.

MR. BATTELLE: Keith Battelle, California.

MR. WOMM: Girard Womm, California Department of Health Services.

MR. ALAMO: Terry Alamo, California.

MS. BOEK: Heidi Boek, New York State Energy Authority.

MR. VANGUARD: Richard Vanguard, NRC.

MR. LOHOUSE: Paul Lohouse, NRC.

MR. McDANIEL: Keith McDaniel, NRC.

MR. BALDMOY: Paul Baldmoy, DHS, California.

MR. HICKMAN: John Hickman, the City of California, DHS.

MS. YOUNGBIRD: Barbara Youngbird, New York State Environmental Conservation.

MR. FURY: Ken Fury, California.

MS. HENNER: Kathleen Henner, California.

MS. SCHNEIDER: Kathy Schneider, NRC.

MR. BOLLING: Lloyd Bolling, NRC.

FACILITATOR CAMERON: All right. Well, that will give everybody an idea of who's out here. That went so well maybe we should quit while we're ahead. We're going to forge ahead. Don, would you like to start off?

"MINI" WORKSHOP: THE NRC'S MEDICAL RULEMAKING INITIATIVE

DR. COOL: Okay. Good morning. I'll have to figure out exactly how far I should hold or not hold this so that I don't either blow myself out or you can't hear me.

I want to spend the first couple of minutes just making sure that we are all understanding where we have been and where we are going through this process for the revision of Part 35. I don't really need to see my name very long.

As most of you are acutely, perhaps chronically aware of the history, the Nuclear Regulatory Commission and the states have been looking at the issues regarding medical for a long period of time.

At NRC, there were a series of reviews, an internal review conducted in 1993. There was an external review contracted by the NRC with the National Academy of Sciences-Institute of Medicine report published a couple of years ago now.

That moved into the strategic assessment process, which Chairman Jackson talked to you about on the first morning of this meeting. The results of that process came out through a series of staff requirements memo. That's what the SRM on that first line means for those of you who are not familiar with another one of the many, many, many NRC acronyms. That is the mechanism by which the Commission gives the staff specific directions, instructions, approvals, denials, et cetera.

The particular strategic issue that the Commission addressed in this particular arena was Direction-Setting Issue Number 7 on materials medical regulation. The items which were in that SRM started, first and foremost, with a reaffirmation of the basic NRC program in the materials and the regulation area.

From there, it moved to a whole series of rather more specific directions with regards to the actual revision of 10 CFR Part 35. That was, first and foremost, to try and refocus the rule towards procedures that pose the highest risk, consider alternatives for the diagnostic procedures consistent with risk, to try and capture the relevant safety issues in precursors. We'll be talking some more about what that means and what the possibilities are for capture, which is an interesting term.

They directed us to look at changing the term of misadministration to medical event or some other term. They didn't specify what it was. They asked us to look at trying to redesign the rule to allow for more timely incorporation of new modalities and activities. They asked us to take a hard look at the quality management program and to try and focus that on patient safety.

The SRM, in fact, went into a little bit more detail than what I wanted to try and squeeze on this slide in terms of potentially focusing simply on some of the primary objectives and getting rid of some of the other detail which exists in the current rule.

I'm actually a little bit surprised that Ed Bailey isn't already clapping. Are you awake, Ed?

MR. BAILEY: Yes.

DR. COOL: Thank you.

And they asked us to look at to what extent we could use available industry guidance and standards in terms of facilitating either the rule or the guidance that would go allow with that rule.

The Commission and the staff requirements SRM also give us a very tight time line associated with this rulemaking. They told us that they we had to bring them a final rule by June of 1999, no ifs, no ands, no buts, no excuses.

We, in fact, tried going back and telling them that it really would warrant taking a little bit longer to make sure we had gone through a proper and a process and had some time to consider some of these issues. They came back and said, "No. You didn't listen to us the first time. We said June of '99. Be done."

So we are in a process, which we have up on the schedule. We're running a series of facilitated meetings this fall, this meeting being one of those. We'll talk a little bit more about those in a little bit.

In order to accomplish the overall time line, we need to have a proposed rule to the Commission in the Spring of '98, the actual official public comment period required by the Administrative Procedures Act that summer so that we can have a final rule back to the Commission in the Spring of 1999.

We are, in fact, trying to get as much input as possible given the short time frames that we have available to us before trying to get a rule back up to the Commission.

There have been a number of meetings with various professional societies and activities. Cathy Haney, in fact, is on the second leg of a grand world tour of the United States, started out in Chicago and will end up in Orlando tomorrow for the ASTRO meeting. We met with ACNP and SNM, ACR, a number of the other folks to the extent that we would try to get on their schedules and have some time available.

We have the public meetings, which I'll talk about in a moment. And we have the materials which are available, the things that we're going to be talking about today and as we continue to move forward some of the other materials as they are developed on the NRC Web site.

For those who are in the States, you've already heard a little description. Once the technical forum actually residers out on this coast on a server, you can get to it from the NRC home page. It is a little bit circuitous in that you have to click on "Public Participation" and then discover that there is a little line about the second line down of things that you can click on that says, "Rulemaking." And that's how you

eventually work your way through the process. It's not exactly the most user-friendly home page. We have to see if we can continue to try and refine that so it's a little bit easier for you to find.

The public meetings. We are here today meeting with the states, in particular, as the group around the table and the folks on the West Coast. In two weeks, we will be in downtown Philadelphia. A couple of weeks after that, we will be in Chicago to go through these same sorts of discussions.

For those of you who want to write down the actual detailed location of the NRC technical forum, you can try and write that down. We'll put that up later. I've got the copy here. I don't know that you want to spend a whole lot of time. But if you ever get it typed in right and find it, I would suggest you put a bookmark on it because there are enough letters and dots and colons and things in there to make typing it in each time extraordinarily aggravating.

I want to spend just a moment or two before we move into some of the other issues talking about the issue of risk. The Commission asked the staff to try and construct a rule that was more risk-informed, performance-based.

Now that, as Chip has said, has become a catch phrase around the Commission in terms of a theme, in terms of an approach for all of the regulatory activities that we're pursuing, not just medical, not just materials, but reactors in every place else.

If you're talking about reactors, it's fairly simple, actually, to think about what risk-informed and performance-based might be. There was a relatively well-developed methodology, PRA types of analyses. Most of the reactors have had Level II, Level III PRAs done, and there's a great deal of experience, a body of knowledge and practice, that has gone on with that. And it deals with traditional radiation protection, nuclear safety-type things of keeping people and radiation as far apart as possible and keeping the dose as low as reasonably achievable, preferably none at all.

Well, as you know, medical is the one place where that kind of paradigm simply doesn't hold up. And so one of the issues that we have to try and deal with her is what risk means in Part 35 and how to best look at risk because there's occupational risk. Certainly there's physicians, there are nurses, technicians, and other people who are working with it on a daily basis, for which there is occupational exposure being involved.

There is dose to members of the public as a result of a patient who has been discharged, other activities, other people in the hospital who are not associated in any way with the activities.

But then there's this subcategory of those folks who are nominally members of the public. They're referred to as patients. And they're there to receive some kind of treatment, receive some kind of benefit from whatever the medical community can provide in terms of diagnosis and therapy to try and cure or diagnose particular disease processes. That means that we are, in fact, in a position of putting the radiation and the people together deliberately and specifically to accomplish a purpose. So at that point, minimizing dose does no longer serve as a reasonable expectation.

Now, maybe minimizing in the context of getting the best image possible without getting any more material than necessary has some sense. But if you're on the therapy side of the arena, an under dose is just as bad perhaps or more so as an overdose because you haven't, in fact, accomplished the purpose that you've intended to do, which is to destroy some part of the human body which is diseased, the cancerous tissue or whatever it may be, and leave the rest of it untouched and functioning so as

to allow an individual to continue to live with the quality of life.

So the item that we want to put on the table very briefly, first of all, is how those three very different types of risks might or might not play into the issues in terms of constructing this rule and to what extent different kinds of modalities or practices within the overall use of radioactive materials in medicine could be categorized into lower risk or higher risk.

Quite frankly, we have looked at some of the ones. You get traditional radiation protection people, and they'll say, "Well, that's fine. Anything less than X dose has got to be low risk. And anything greater than Y dose has obviously got to be high risk. And in between, there might be some things that are in the middle."

While that maybe has some logic to it and is attractive to some of us who like to draw nice, neat, little square lines all the way down the page in terms of having it match up with the other requirements for occupational and public exposure, it's not totally clear to me yet at this point. That's why we're asking the question as to whether or not that forms a reasonable basis for risk.

Part 35, of course, has always had or for a very long period of time had some various things

associated with it. And there were some categorizations. In theory, the 100, 200, 300 types of levels were based, at least to some extent, on risk or you could look at it and say, "Well, all things that are diagnostic, you should consider as low. And all things that are therapy, you should consider as high." But those sort of blur in the middle.

And so what I wanted to do -- and I'll turn it back to Chip now -- is to have a brief discussion on what is low risk and what is high risk as we proceed through looking at this and trying to get the Commission's direction in terms of a risk-informed rule.

FACILITATOR CAMERON: Okay. Thanks, Don. In addition to the risk issue, are there any questions about schedule format? Probably get those out of the way now. But the major substantive area here is this over-arching issue of risk.

Who would like to start us out with comment on this? Ed Bailey?

MR. BAILEY: Bailey from California.

I think when we were looking at risk in the medical setting, a recent experience I had with going to visit a gammonite facility and literally being there through the whole process of the physicians and physicists working at the treatment plan sort of interactively --

I'll have to admit I wasn't there when they drilled the holes in the woman's head to put the brace on, but seeing the woman walk into the gammonite, be treated in a period of about 15 minutes, and walk about. During this process, which overall took three, four, five hours, there were two radiologists, two medical physicists, someone I don't know what her job was, but she was visiting.

Anyway, in talking to the doctors afterwards, it was treating some sort of tumor someplace down in the ear with a long name. And they described what would happen if that woman had not had that kind of treatment.

She would have had approximately 12 hours of surgery where the physician was looking in her ear with a microscope to see how to cut and scrape. And she would have been hospitalized for like two weeks. And to me the risk of some error from that gammonite treatment paled in comparison to the risk that was associated with the alternative procedure and, quite frankly, the pain and discomfort and cost.

The cost for the treatment was like $25,000. The alternative they said was over a quarter of a million. So I think when we start looking at risk in a medical setting, we have to weigh not just the radiation risk and the possibility that there's going to be physical injury, cancer-induced, or some genetic problem as a result of it.

We've got to look at what the risk is to that individual patient compared to no treatment or an alternative treatment.

FACILITATOR CAMERON: Okay. I think that's a great opening comment that risk isn't just measured in a vacuum.

Aubrey?

MR. GODWIN: I would submit to you an additional problem when you start dealing with risk and try to do simple mathematical calculations. You have to choose a model. And whether you choose a linear, no-threshold, or threshold model makes a lot of difference as to what you come up with, whether you're looking at economics or whether you're looking at injury.

I think that the current models that were used by many, particularly EPA agency types, to estimate risks are wrong. Now, I think there should be a real serious look at whether the linear, no-threshold model is the applicable model that should be applied.

I would urge the Commission and the Commission staff to really take a hard look at that. This may sound like heresy, but I really think that there's sufficient evidence to justify a real hard look at this.

I also support the comments of Ed. I think that it's going to be very difficult to do a risk

evaluation when you're talking one on one because the risk on low numbers becomes a rather foolish statistical act. So you really need to look very carefully before you try to tread into these waters.

FACILITATOR CAMERON: And I just would remind everybody to try to speak into the microphone. I think we're a little bit low again.

Don, do you have any context that you want to put onto Aubrey's statement in terms of one of your initial questions of how do you place these different modalities into high, low, medium risk?

DR. COOL: Well, Aubrey is quite right, of course, in terms of the assumption you make about the radiation dose risk and the assumption you make about linear or nonlinear. There are, in fact, a whole series of exercises going on which NRC is a part of in terms of funding for the new B.E.I.R. study which is ongoing and some of those activities.

I would expect that some of you probably will smirk at that particular reference because you may or may not believe that such a group will take a look in the way that you would want them to take a look.

That is certainly an issue which will play out. I suspect, quite frankly, that that is going to play out over a much longer time frame that we have in this

particular rule activity, but it's one that I agree with you needs to continue to be looked at.

FACILITATOR CAMERON: Thanks, Don.

Mike Mobley?

MR. MOBLEY: Mike Mobley from Tennessee.

I hear what Ed and Aubrey are saying. And I agree with it. I mean, you've got to consider these issues. But I think there are other considerations that you have to fold in there. My statement is probably going to be a little broader, although Aubrey by going all the way back down to the theory of radiation impacts, radiation risk, that's pretty broad.

Anyway, let me just make a few comments to provide perspective I think when you're evaluating risk. It concerns me considerably that we seem to be going in two different directions in this country at the present time.

We have the somewhat EPA-driven, although it may not be wholly EPA-driven, perspective regarding waste disposal and certain kinds of radiation practices that are being driven down to near zero impacts at an extraordinary cost.

We have in the medical arena, in particular, a perception that, well, cost is really important and we've got to look at all of these things and we're moving away

from things that have generally been pretty standard in radiation protection, you know, holding the patient in the hospital until the doses were below a certain level or whatever.

At this meeting, something that I predicted some time ago we see occurring. And that is we are seeing more material out there in landfills, dumpsters, medical incinerators, laboratories, some of which is very significant.

When you have sample material sitting around in non-radiation arenas that's reading MR per hour levels for long periods of time, people are getting exposure to this. And you look at that, and you say, "Wait a minute. You know, if we were disposing of that as low-level waste, it would be over here. And you couldn't expose anybody in 500 years to more than 25 millirem from that."

Somehow we've got to put some balance here to make sure that we're not getting ourselves into a situation where we have patients that are out there walking around that have a lot of radioactive material and are exposing a lot of the public; whereas, we're spending a lot of money over here trying to reduce some hypothetical exposure. Now, that's a broad issue there, but I think it's one that we do have to keep in mind as we go along here.

And one more statement. I'm not going to be here too long this morning. So I want to get this one in. It's interesting to me on these medical events that we're calling them -- and I'm not a physician. So I'm open to understanding.

But I read these things, and I see that John Doe got 25 percent more than what he was supposed to get. I don't think I've read one yet where they said that's a problem. It's always that didn't make any difference. Okay. No problem.

And I'm always hearing about, "Man, we're down to five percent. We do these doses within five percent of what we want to, and that's critical," et cetera, et cetera, et cetera. But then we get a 25 percent overexposure to an area or to the patient or whatever.

It's not a problem. I don't understand. I need some help in that arena.

FACILITATOR CAMERON: I think you're probably going to get some help.

(Laughter.)

FACILITATOR CAMERON: And I hope you don't have a plane to catch anytime soon.

MR. MOBLEY: I do, and I will.

FACILITATOR CAMERON: Ray?

MR. PARIS: I think for the purpose of this discussion, we need to focus on what risk we're trying to talk about. Is it patient risk? Is it occupational? What are we trying to resolve here? I can't quite focus on where we're going. So let's define the arena of risk that we want to discuss and then go from there.

DR. COOL: Let me suggest a framework. You can disagree with the framework. Many probably will -- which is that occupational and general public ought in general to be covered by the NRC's general radiation protection standards or your equivalents, as in Part 20, and that perhaps the ranking associated with risk and the things that need to be looked at in terms of the Part 35 or your equivalents in the States perhaps should be driven more by the patient.

Those were some very interesting observations that Mike made. And that really gets to the crux of the matter. Around Washington, it gets called the Washington Post smell test sometimes, sometimes referred to as the outreach factor, which is the difference between what we around here might agree and talk about in terms of risk or not risk and amounts of material that ought to just be disposed of and what actually happens when somebody's detector at the landfill trips off because there's a diaper.

FACILITATOR CAMERON: Okay. I think that was a useful construct.

Let's go to Richard and Steve and then get some comment from the public on these issues. Richard?

MR. RATLIFFE: Yes. Richard Ratliffe with the Texas Department of Health.

I think with what Don just said, it falls right into what I was going to talk about. You know, we look at the public risk from X-ray and accelerators. And once it's turned off, there's no risk outside of the plant or the hospital. The patient's risk. I really think we've got to make sure that we look at what is practiced medicine and what is our role as protection of public health and safety.

The more important part I think that we have to do is the occupational risk. And I think we're really doing a disservice if we don't really look at the area. The NRC only looks at byproduct materials. But I know in Texas, when we look at the occupational risk, cardiologists and floor units, we have the highest doses when we look at someone coming in to a VA hospital and they only look at agreement material but there's radium sources there, I think the occupational risk is a composite of the agreement materials, the norm, the narm, and the machine to produce radiation. And if you don't

look at all of those risks as a combined risk, you're really missing the point on the occupational side.

FACILITATOR CAMERON: Okay. Thank you, Richard.

Steve?

MR. COLLINS: Steve Collins from Illinois.

I'll agree with Don on the first two items when he talked about application of Part 20, but basing Part 35 on patient risk is -- how can I be kind? I don't agree with it.

To me, most of the patient risk area, most all of it, should be reserved to the risk-benefit decision of the physician and that NRC and the states shouldn't inject themselves into that very much.

We ought to keep our focus on worker, occupational, member of the public stuff and require, somehow or the other, that people that are trained, qualified, and experienced in this area make those decisions and put up the procedures to guide their staff in some manner to make those risk-benefit decisions for the patient.

If you are going to go to a modality approach in Part 35, it's not going to be based on patient risk anyway. It's going to be based on convenient dividers,

based on type of equipment or processes being used. And it's a matter of convenience.

Also I would say that in the Part 20 stuff, the risk-informed is once again a risk-benefit type weighting that we have to do. And whether it's high or low would be couched in terms of: Is it about as low as it can reasonably get to without spending too awfully much money of the health care dollar on it?

FACILITATOR CAMERON: Thanks, Steve. I'm going to take one more card that's up before we go on here. Steve, if you could just revisit, help refresh us as we go through these other areas with that sort of underlying concept, and bring that out to the floor when we get into the specifics?

Aaron, do you have a comment?

MR. PADGETT: Yes. I guess I'm just a bit confused after one comment that Don made. Which public standard are we talking about? Because now I have one that says maximum of 100 millirem with ALARA applied below that. I have another that says 500 millirem that applies to the release of patients. And now I have two standards. And I'm a little confused as to what public standard we're talking about.

FACILITATOR CAMERON: It sounds like a question for you, Don.

DR. COOL: Welcome to the controversy.

MR. PADGETT: Right.

DR. COOL: As you know, Part 20's basic public limit is 100 millirem per year. Part 20 also contains an alternative which licensees could apply for under certain limited circumstances to go to 500.

The Commission now over a year ago agreed that release of patient constituted a limited sort of situation in a general sort of construct such that that release could be at the 500-millirem level because it was not likely to be replicated a large number of times. And there were a number of other arguments.

That construct is, in fact, limited to release of patients. It's why it's contained in the present Part 35.75 and is not generally applicable to all of the other areas. I will tell you that there is a similar rule presently under consideration which would apply to individuals who would be visiting a patient in their rooms to have a matched construct in terms of that amount.

But it does exactly. It would, in essence, say that if you had someone you were close to, wife, daughter, grandmother, something like that, who was under treatment, that it would be allowable for you to have perhaps ten times what NRC would normally allow any member of the public in the combination of visiting that

individual, providing for them while they were in the hospital, and then after they were released if they had had perhaps a therapy treatment with iodine or something like that.

MR. PADGETT: Just a quick response, if I may. I understand that. And I'm moving real quickly to allow the release of patients where a member of the public might get to 500 millirem.

However, every physician who is an authorized user in North Carolina is going to be allowed to release patients. So we're going to have a number of members of the public who exceed 100 millirem.

I come back to the problem that Mike has. I'm also regulating, helping regulate, the development of a low-level waste site. And there we're seeing: Hey, if anybody out to 10,000 years at any point in time can get 25 millirem, you can't open this site. Where is the logic?

FACILITATOR CAMERON: And keep in mind that this larger issue of risk comparison, I'm not sure that the Part 35 rulemaking is going to be able to bear the weight of all of that, though those are good issues.

I'm going to go out to get some comment from the public. I don't know if we'll ever be able to close on it, but the million-dollar question is still: How do

you characterize areas of low, high, in-between risk here? Carol, do you have a comment? You can go over to that mike. It would probably be easier.

DR. MARCUS: Obviously the way to do medical risk is something that people in the medical profession have worked on for many, many years. It's new for the NRC to be looking at the whole area of what is involved in a medical risk analysis, but there is a lot of help out there.

Recently, in 1997, a Presidential-Congressional Commission on Risk Analysis and Risk Management published their final report. I've given a copy of the first volume to Chip Cameron. It really is the most important one for our purposes.

And I think one of the most important components of this is that you must look broadly when you analyze the risk of any activity or, else, you end up looking at something that isn't very important at all and ignoring something that is terribly important.

There's a short paper by Ralph Keeting that I've given to Chip as well that was published in the New England Journal of Medicine, which is one of our most prestigious medical journals, by one of the best risk analysts in the country. And it's our medical risk.

One of the things you have to keep in mind as you look at risk here is that the cost of regulation is a very important aspect when you look at risk, just cost itself. In 1997 dollars, you average for every $12 million that is spent on regulation, good regulation or bad regulation, -- it doesn't matter -- but for every $12 million spent on it, one random person dies.

And they die because you didn't spend that money fixing the roads, getting new tires for your car, getting better health insurance, or doing other things with the money that enhances your safety.

The trick is to show that for every $12 million that's spent on regulation, you save many more than one person because you're going to kill one, no matter what you do, statistically.

The cost of NRC's medical regulation, basically nuclear medicine regulation, is not in user fees. The cost of complying with all the license conditions and requirements and regulations in the United States is about a billion dollars a year, including all the agreement states and including accelerated produced materials. That comes to about 83 random deaths a year.

NRC had better be showing that with all of these costs, whether they're reasonable requirements or not, that they are saving more, a lot more, than 83

people. And when you bear in mind that in nuclear medicine, since 1936, we have done over a quarter of a billion procedures in this country and there is one radiation death from nuclear medicine, it doesn't seem offhand that this risk balance is going to come out very much in favor of spending a lot of money on regulation.

One of the other things you have to look at is the risk of a patient not being treated at all. There are states in the United States, mainly in the far West, where very few physicians will touch nuclear medicine therapy because of the onerousness of the queimeral, where patients go to Salt Lake City for their therapies because they can't conveniently get access in their own states.

If you have someone with Grave's disease -- these are usually young women with little children -- who get heart attacks or strokes because they didn't get help quickly, that is a terrible risk to that patient. And you really have to ask whether what you're doing to protect people is more than what you're doing to harm a young woman with an untreated Grave's disease.

You also have to look at the risk of alternative procedures if people decide your regulations are so onerous that they won't use them. And you will find that there are alternatives to any nuclear medicine procedures.

Often they have more radiation attached to them. A pulmonary angiogram, for example, is an invasive procedure. It has many risks that have nothing to do with radiation at all. And then it has about four times the radiation that a nuclear medicine lung scan has. So that's one of the components of risk when you do an analysis.

The point that several of you have brought up, -- I think Aubrey might have been the first one -- the linear no-threshold hypothesis -- we all know the health physics stand.

What you may or may not know is that soon afterwards, the American College of Nuclear Physicians supported it unanimously. And at its last meeting, the Society of Nuclear Medicine did so, too.

So you really have a large contingency of professionals who just don't believe that this tiny, little millirem amounts are worth arguing about. The consternation shared by many of you that 21 millirem is sin in one context and in another it has to be over 500, it is silly. It's a separate issue to deal with.

But we can't really find risk in workers who get exposed to levels up to five rem. So why are we fooling around with very low levels, levels that people

who live in Colorado get every year? In Colorado, it's tied for the third lowest cancer death rate in the nation.

FACILITATOR CAMERON: Carol, I'm going to ask you to just stop with that thought. That was a good summary, I think, of what went on around the table and some good thoughts for the NRC. If we have time at the end of the day, we're going to go back and see if we can elaborate on this.

Dr. White, did you want to say anything at this point? We will come back up to the table and finish this part of the discussion off quickly. And we're going to go to medical policy statement next.

DR. WHITE: Thank you very much.

I have a prepared statement I'd like to read for the record and then some comments I'd like to make. I'll make it as brief as possible.

I'm here representing the Nuclear Medicine Physicians of California. The Nuclear Medicine Physicians of California are pleased at the progress we are making with the California Radiologic Health Branch in improving the quality of nuclear medicine regulation in California.

We believe that NRC's new regulations should be an item of compatibility at no level greater than information.

(Laughter.)

DR. WHITE: We continue to believe that the adequacy and compatibility provisions of the Atomic Energy Act refer to the standards of Part 20 and do not extend to medical and pharmacy practice.

We believe that if NRC's new Part 35 is of excellent quality, -- and we hope it is -- then the agreement states will be eager to embrace it voluntarily. They shouldn't be forced into it.

However, this would require a consensus document between NRC and professional and regulatory stakeholders. And we urge NRC to insist upon such consensus. NRC commissioned a two-year, two and a quarter million-dollar National Academy of Sciences' internal Institute of Medicine study of its medical regulatory program. And the report was issued in December 1995.

It appears that the report has not been read at NRC or it has fallen on deaf ears. We believe that the quality of the report is excellent and the NRC needs to address the criticisms and suggestions made by the NAS-IOM.

As this has not yet satisfactorily occurred, we urge NRC to begin to do so. After all, the conclusions of the NAS-IOM were not only recommended by the Society of Nuclear Medicine and the American College of Nuclear

Physicians but by Commissioner E. Gail dePlunk and Chairman Ivan Sullivan as well.

Despite assurance of comprehensive risk analysis for medical regulation by Chairman Jackson, no risk analysis has been produced. And none appears to be in the pipeline. We believe that a risk analysis compatible with the guidelines of the Presidential-Congressional Commission on Risk Analysis and Risk Management is essential as a framework for new regulatory paradigms.

Despite Dr. Cool's promise that NRC would reconsider a Part 35 rewrite with a, quotes, "clean sheet of paper," end quotes, it appears from a recent ACMUI meeting that only very limited choices are being considered by NRC. And those choices do not represent any innovative change. This is not acceptable.

Although the Commission promised ACNP and SNM a partnership process, we are not even represented at any of the working groups. We, therefore, strongly urge NRC to heavily weigh our input at public meetings.

Even if NRC's new regulations were to be excellent, we have concerns that NRC would remove via licensing what it gives us by regulation. This is a problem with three draft guides that NRC has recently

produced for manufacturers; physicians; and pharmacies; and, for one final guide, for the patient discharge rule.

In addition to questioning the content of these guides, we question even the need for guides at all. We believe that NRC has to address this problem. Due to our unresolved concerns, we do not wish California or any other agreement state to be forced to adopt any of the new Part 35 or its accompanying regulatory and licensing guides.

For decades, NRC did not interfere with agreement state medical and pharmacy programs. The recent NRC interest in controlling these programs appears to have a significant economic component.

While the Atomic Energy Act as amended encouraged the formation of agreement states, the Congress in 1990 required that NRC obtain virtually all its operating funds from user fees. As more and more licensees paid agreement states, instead of NRC, NRC staff faced eventual cutbacks. It's not surprising NRC would try to stop more states from beginning agreement states, threaten to take back programs, or make compatibility so expensive that the governors would give back their programs to NRC.

Asking the NRC staff to encourage the demise of their own positions is probably asking too much. If

the commissioners of NRC do not satisfactorily address this issue, then the Congress must intervene to stop a bad situation which the Congress inadvertently created.

We continue to believe that the most pressing problem in nuclear medicine is the erosion of qualifications for authorized users. The quality of nuclear medicine practice is suffering significantly as a result. We continue to strongly recommend that NRC and the agreement states require evidence of mastery of quantitative radiation protection science and significant hands-on experience with radioactive materials before permitting any physician to be an authorized user.

No lower qualifications than that of the ACGME should be accepted by NRC or agreement states. Whether or not such physicians have the medical qualifications to practice nuclear medicine should then squarely be put into the hands of practice privilege committees, the Joint Commission on Accreditation of Health Organizations, and state boards of medicine.

In addition to that statement, I would like to touch briefly on the economics of rulemaking in the private practice of nuclear medicine. There are some very stringent pressures being placed on the private practice of nuclear medicine today, in medicine in general

throughout the country. But it impacts greatly on the private practice.

With agencies like the Health Care Financing Administration, HMOs, PPOs, any other form of managed care that you can conjure up, there is an absolute ceiling placed on payments. One can charge whatever one wants. The bottom line is what one gets paid, hospitals, physicians, any other providers. With an absolute limit on what they're paying, one cannot any longer pass on costs that are laid on an individual for the practice.

As Dr. Marcus mentioned, there's a billion dollars equivalent in satisfying and complying with the regulations of NRC for nuclear medicine. That equates to roughly $100 per scan in this country. That's an expense that cannot be passed on to the insurers any longer. The individuals who are performing it, the hospitals, offices, physicians have to eat that, one way or another.

The hospitals are under pressure from all sorts of other aspects in the pay arena, and they are constantly having to reduce their costs. The major areas they're doing that in is personnel.

Employees are being laid off left and right. If any of you have been to the hospital lately, you'll notice that the people taking care of you in the hospital bed are no longer wearing R.N. pins. They're L.P.N.'s,

aides, assistants, what have you. There will be one nurse covering multiple patients with a whole series of non-nurse people taking care of you. That's because of economics.

The same thing is happening in our department in nuclear medicine. My technical staff has been cut back dramatically. We have no clerical staff. We just don't have the people that are required to take of these paper chases for regulations that really have nothing to do with the quality of the care of the patient, nothing to do with the safety, either direct or nuclear-type safety, radiation safety, for any patient. In other words, all of this extra work and pay is being put out for no benefit to the patient.

Thank you very much.

FACILITATOR CAMERON: Okay. Thank you very much, Dr. White.

We do have to move on here. There are many points that were made that we could debate endlessly and constructively. The one point that was made was the suggestion of a risk analysis done according to the guidelines of the Presidential Commission on Risk. At some point, it might be useful to get people's viewpoints about whether that's feasible, how it should be pursued, whatever.

Let's close this out with Terry and then Don Flater, who has had his card up for a while. Terry, go ahead,

MR. FRAZEE: Terry Frazee, State of Washington.

Just going back and addressing the question that you originally posed of high-risk, low-risk. And I think in the context, I would view it as being an issue of harm. Generally diagnostic procedures, as Mike indicated, there's never any harm with what was called misadministration.

On the other hand, we know what real harm is. There have been patients that have died as a result of radiation exposure, typically not in nuclear medicine or even in therapy or therapy from machines. Accelerators have killed people.

So I think from my standpoint, the high risk, low risk, it's: Is real harm being done to a patient? And perhaps the guideline is $LD_{50/30}$, you know, what's a lethal dose.

FACILITATOR CAMERON: Could you just explain for those of us who don't know LD, the numbers? Obviously I don't know.

MR. FRAZEE: LD means lethal dose. It would be a lethal dose to 50 percent of the population exposed

over a 30-day period. It happened to be the one I picked. It could be different but a lethal dose to the population exposed.

FACILITATOR CAMERON: Okay. Thank you, Terry.

MR. FLATER: One concern I have is that we have been spending a whole lot of time talking about global things. And there's one thing that hasn't been brought up. And it's a concern.

These global things are all fine, but what do you do with the physician, technologist, whatever that isn't competent? I'm not talking about anybody in this audience because I'm sure they all are. But there are some out in our less populated areas where we have people, doctors, technologists, physicists that just flat aren't competent.

And I would hope in this global issue where we're turning loose of everything we don't lose of the need to be able to deal with the issue of incompetency on a very small group of people.

FACILITATOR CAMERON: Okay. Thank you. I think we're going to be coming back to that issue in training and experience.

Don, do you want to, or Cathy, talk about the policy statement?

DR. COOL: Okay. Let's go ahead and move to the next. I want to turn this to Cathy Haney, who is my section leader working on the rule, who will give you a very brief overview of the options that were laid out.

Let me preface all of these. I think she will probably give you the same preface again. These were options which were constructed by the working group. They were constructed keeping in mind the guidelines which the Commission had given us in the staff requirements but did put some boundaries on what we could or could not consider.

These are not intended to be all-inclusive. If you can come up with something that you believe would work better, that's what we're here today to try and hear or if it's some combination, it's part of this and part of this and part of this one, to create effectively another option. That's what we're here today to try and do. So if you have some other idea that is within the bounds of what the Commission gave us in terms of guidelines, we're very much interested in hearing those.

One quick administrative matter for our stenographer here who's keeping the transcript. For those of you, particularly members of the public and the audience who are making presentations, if you could stop by and see him at some point so that he can make sure that

he get your names correct for the record, I think that would be much appreciated.

Cathy?

MS. HANEY: Good morning. I'd like to take about two minutes and just tell you a little bit about the working group. As you see from the slide, these are the groups within NRC and the states that each has provided a representative to the working group.

I am chair of the group. We have representatives from the State of Ohio and the State of Alabama. They were introduced to you this morning. We have had one formal meeting of the working group so far. That was in August. And that was when we spoke about these alternatives and basically what it was going to take to get the rule done in the two-year period.

We're also using a steering group approach where the work that's coming from the working group is then reviewed by the steering group. Again, it's important to note here that we do have agreement state involvement on the group. Tom Hill is sitting on the steering group.

At our first meeting, we discussed several items. And those items we'll go through with you today. One is recommendations for revisions in the NRC's medical policy statement.

In the Commission's SRM, they asked that we look at this and decide if change is needed to be made to the policy statement. We also looked at the patient notification requirements, requirements for radiation safety committee, training and experience in this area.

We looked at those primarily for the authorized user but also for the radiation safety officer, medical physicist. And we did touch on whether we needed to be looking at any training requirements for ancillary personnel. We looked at the quality management program and the threshold of reportable events.

Also at that meeting we took a little bit of time to talk about the structure of Part 35. I think it's important to just show you at least our preliminary discussions on the structure so that you can see where some of these items that we'll be speaking about today fit in and also get maybe your viewpoints on where you think they should fill in.

Basically we saw the rule being structured into a general administrative section, a general/technical, and then going into the modality-specific sections. At least for right now, these are the modalities that we have identified.

As would be applicable, the thing to note here is that the emerging technology -- this is our attempt at

trying to find a place to fit in any of the new emerging technologies that would come about that wouldn't fit into any of the other categories.

Then we would have a recordkeeping section and a reporting section. And the last would be the enforcement. Now, this is not the enforcement policy for Part 35. This is merely the two or three paragraphs that exist at the end of the current Part 35 that just say that we can issue an order if we have to, those kind of catch-all paragraphs.

As we go through these different sections today, it would be interesting to get your views on whether these topics belong up in these general, administrative, and technical sections or whether they go down in the modality.

Let me give you an example, something like a radiation safety committee. Right now that requirement could possibly go into a general/administrative section. But would there be a need to put that down and to just make it modality-specific?

Training and experience requirements lend itself very easily to the modality-specific sections. But, again, I thought it would be worth taking a section to show you the basic outline. We're following this

outline. It's very similar to what was used in Part 20 and Part 34.

All right. Now I'll start with what I was supposed to talk about: the medical policy statement. Basically this was developed in 1979, and it was to address NRC's role in the medical area.

What you see up there right now -- and I'll take a second to read through it for those who aren't able to see it, what it says. This is the current policy. It says, "one that NRC will continue to regulate the medical uses of radioisotopes as necessary to provide for the radiation safety of workers in the general public." As we go through the alternatives, this one tended to stay. There were no changes made to this item in general.

The second item, "The NRC will regulate the radiation safety of patients where justified by the risk to patients and where voluntary standards or compliance with these standards are inadequate."

The third statement is that the NRC will minimize intrusion into medical judgments affecting patients and into other areas traditionally considered to be a part of the practice of medicine. As I said, that's how the policy stands now.

This policy was discussed with the ACMUI at their April meeting, where they made some recommendations.

This was prior to us or it was immediately after we got the direction to go forth with the change with Part 35.

It was again addressed with the ACMUI at their meeting that took place two weeks ago. They made some minor changes to this particular item, and I'll focus in on that in a second.

The key difference between this particular item and the current policy is the last statement that's underlined in Number 2 that the assessment of the risk justifying such regulations will reference comparable risks and comparable modes of regulations for other types of medical practice.

Also, in the third statement, the key is here that the NRC will not intrude into medical judgments. They made it much stronger than what it currently is right now.

The ACMUI in the meeting that took place two weeks ago asked that Statement 2 and 3 switch; in other words, 3 becomes 2 and 2 becomes 3. They also asked that a change be made in that sentence to bring in the second sentence under Number 2, to bring in voluntary standards such that it would say assessment of the risk justifying such regulations will reference comparable risks and comparable voluntary standards and types of medical practice.

From here, the working group looked at some other approaches that we could take to revising the policy statement. In the case of Option 3 -- and I'm not going to read through this, but basically we strengthen Statement 2, bringing in the fact that we would only regulate only where justified by the risk to the patient.

In Number 3, we were proposing revising it to state that we will continually strive to minimize involvement in medical practice. In other words, there are some slight differences from the current policy statement, but it's not very significantly changed.

Option 4 does have a rather significant change in it. In other words, in Statement 1, as I said, there's still no change in it. Number 2 says that "NRC will regulate the radiation safety of patients consistent with the risks posed by the radioactive materials. In regulating the radiation safety of patients, NRC's role is to assure that the physician's prescription is accurately delivered to the correct patient." And then again in Statement 3, we're making it clear that NRC will not intrude into the medical judgment forming the basis of the physician's prescription.

This particular option is probably the furthest from where we are currently. And I think I'll probably flip between 1 and 4 as necessary if the

discussion needs it or if you want, basically you can tell me what one you want me to put on the screen. Unfortunately, I don't have copies for you, but I'll be happy to go back to it.

So what we're looking for is: Is there one of these options that you prefer more than another or are there some changes that we have not thought of that you would like to put on the record?

FACILITATOR CAMERON: Let me just say two things to start this off. One, these are options that the staff has come up with in order to try to capture the full spectrum of possibilities. There may be options here that no one is going to like, but in order to get the full spectrum out there, they had to be identified.

Secondly, obviously whatever option you choose on the policy statement, the rules for the substantive areas for the modalities or the other cross-cutting issues are going to have to be consistent with that. So the challenge for Don and Cathy at the end of this is to make sure that the options identified in the other areas are consistent with whatever the policy statement is.

Okay. Comments on the policy statement on the options? I think this goes to the heart of the practice of medicine issue that Richard and others brought up. Do

people think the policy statement needs to be changed? Steve, you're reaching for your card.

MR. COLLINS: I agree with Item Number 1 on each of those as no change. For the others, I do strongly believe that the radiation regulator's role should be to ensure by some means, whether or not we do it or we recognize efforts by others to do it, but just ensure that the training and qualifications of those people that are administering the radiation and of those people that are making the decisions on how much to use for what condition, that their training and qualifications in the area of radiation safety and determining risk-benefit for the patients is adequate.

FACILITATOR CAMERON: So this sort of underlines the point that Don made. A question of clarification: Are we working off Option 4 now or --

MS. HANEY: I can go back. Would you like me to go back to the current policy?

FACILITATOR CAMERON: Yes. Why don't you do that? I think that that might be a little less confusing.

Okay. Let's go to Aubrey and see if we can address this coherently.

MR. GODWIN: Probably not. Godwin, Arizona.

I'm not sure which one of those had the comment in it, something talked about comparing with other medical risks or something.

MS. HANEY: That's Alternative 2. That's the one the ACMUI recommended.

MR. GODWIN: The only problem I really have with that - and I think basically it's a good concept -- is that one should look probably at the areas of medicine that have a good and high standard of practice. When you look at overall risk and particularly you go across the country and look at the way medicine is practiced, there is a rather significant variation where it's acceptable risk in some areas versus other areas.

So I think there would have to be some way of judging what is a good and high standard of practice. But I do think -- I just don't see that where nuclear medicine should be that different in terms of risk from other medical procedures where there's a high level of standard of practice.

But I do see that you need to sort of caveat that a little bit. So look at it. I guess it was Number 2.

FACILITATOR CAMERON: Can we go to that Option 2?

MR. GODWIN: That concept would probably be a good one to add into it in some way, but I favor a lot of the comments in there where you look at sort of the overall risk in the practice because the medical risk judgment takes into account sort of the state of the health of the individual involved.

And, as you get into it, the options become less viable either way you go. So you sort of have to look at that trade-off. I mean, it may be desirable to accept more radiation to get better trade-offs. So I think you need to look at that a little bit and see if you might can work that in somehow.

FACILITATOR CAMERON: Okay. Thanks, Aubrey.

It might be useful for Don and Cathy to get a feel of how many of you generally support this type of an addition to the policy or whether anybody is strongly against it. I think Aubrey was pointing out some caveats associated with it.

Ed?

MR. BAILEY: Bailey from California.

I tend to agree with the changes here, but I also agree with Aubrey that if there were words put in that reflected that it was assumed or expected that the highest standards would be the ones that we were shooting for.

I think Steve probably hit the nail on the head as to where we need to be looking is at the training of the users, whether they be physicians or technologists, and that we stop shortcutting the requirements to be an authorized user and we define, clearly define, what the responsibilities of the authorized user are. Are they responsible for evaluating the patient or are they responsible for determining the dose? Are they responsible for yielding or rendering the diagnosis?

I think in many cases, our biggest problems are where the physician is less than totally involved in the patient procedure. It's where the procedure occurs and the doctor is not there.

FACILITATOR CAMERON: Thank you, Ed. And I think you probably have some examples from California about how you tried to work that particular angle in.

Don, do you have a --

MR. BAILEY: Yes. Could I speak to that?

FACILITATOR CAMERON: Yes, sure.

MR. BAILEY: One of the problems we've had throughout this medical discussion is that we felt that we had some conditions that were stupidly simple that really added to the quality of what was going on. The simple requirement that if you were going to give a therapy dose to a patient, the physician had to be in the same room

that it occurred in, the pharmaceutical. Then there was none of this pointing, and the responsibility was placed directly on that physician.

I think those cases where we have had misadministrations of radiopharmaceuticals for therapy in California, without exception, it has been where that regulation was not met.

FACILITATOR CAMERON: Okay. Thank you.

Don, do you want to ask a clarifying question to the --

DR. COOL: Yes. I'd like to get some clarification and perhaps get some other people to input on this. First of all, when we get to the training experience in just a little while, it would be very useful for things like what you just suggested, Ed; in particular, whether it applies to specific modalities, because I have a feeling from what you just said that it may apply to therapy doses, as opposed to a diagnostic scan. Some other things would be very useful to get onto the record.

The other thing which I think would be very helpful to us in terms of trying to put this package together is if there are specific kinds of wordings that people would suggest not necessarily live or online but

giving me some suggestions so that we can try to capture those thoughts, we do have this transcribed.

Also in the context of finishing up this discussion, whether or not you believe that the statement that either this or some modification of it is sufficient to hand in whatever regulatory types of structures, requirements for the physician would be present with the administration of a therapy dose or otherwise, whether the policy is sufficient to allow us to hang those or whether, in fact, you are suggesting it simply needs to be added to the policy statement in order to facilitate that approach.

We may be jumping back and forth here, but what becomes critical for me is whether or not the policy is sufficiently enabling to accomplish those purposes and, conversely, if it is spread too wide to allow what might be perceived as egregious things happening around the edges that you would wish to prevent.

So, with that clarification, some other discussion.

FACILITATOR CAMERON: Okay. We'll be right out to you. Let's take the cards that are up here around the table. I believe let's go to Aaron and Steve and then Tom Hill and Stuart, and then let's go out to the audience.

MR. PADGETT: This is just a logistics comment. We're getting slides flashed up on the screen. I have nothing here to look at. I have to move as you move. And I have not really looked at these things before. So sitting here to try to make meaningful comments or say, "Oh, yes. We support that" to me is unrealistic. I don't think I can do that.

FACILITATOR CAMERON: Point well-taken.

MS. HANEY: These are the only set of slides that you don't have from here on down. All the other alternatives, we do have a slide on them that sets forth the slide.

The background information to these is on the home page. So you can download those or we'll be happy to give you copies of the full statements. Whichever you'd prefer we can get to you.

MR. PADGETT: But you want our comments now, and I'm --

MS. HANEY: Right. We're trying to look more for really philosophical comments. The exact wording, maybe it's nice, but it's not needed at this point. It's more philosophical.

Do we take the approach of looking for a comparison of risk between nuclear medicine and other modes of modality? Are we looking to just limit the

policy statement to only dealing with the patient-physician relationship or do things seem to work fine with the current policy that we have right now?

FACILITATOR CAMERON: That's a good point that Cathy made. Obviously in order to get to where you want to get to in our future interactions with people, those thoughts are going to have to be made available to you.

Steve?

MR. COLLINS: Steve Collins, Illinois.

With this option, I would definitely be in favor of Option 1 and Option 3 and reversing the order of 3 and 2. With regard to Number 2, Don Cool introduced by the way he phrased something earlier a confusion factor for me. And that's the meaning of "NRC will regulate the radiation safety of patients only" because earlier he made the statement that patients are a subset of members of the public.

In my mind, once you go into the medical setting where you're seeking help, you are a patient, not a subset of the member of the public. And you're in the realm of practice of medicine and medical judgments.

I don't know what he's talking about. Is he talking about when you're a patient, that you're sitting in the waiting room being exposed to someone else who is

being injected? Do you have concern about that or is he actually talking about --

FACILITATOR CAMERON: Don, I think you'd better clarify.

MR. COLLINS: -- the use of medicine in the patient?

DR. COOL: I really didn't mean to introduce confusion. Perhaps it's simpler just to drop that construct if that's causing some confusion for you.

There have been some issues raised from time to time about: What about individuals who may be in a waiting room who then are sitting next to someone who has already been administered before the scan? Some of those issues do arise. They don't tend to be a large number of those.

In fact, the Commission has in general, at least by past exercises, taken the view that once you enter the arena of a hospital or clinical practice as a patient, you are then in that category and outside of the realm of a member of the public.

But you magically switch that when you walk through the door, which is always an interesting sort of concept that I am this and then I am that. But don't push that any further.

MR. COLLINS: Okay. I understand that well. Then I would like for some of you who were present at the ACMUI meeting where ACMUI developed these three statements to explain to me how 2 and 3 are not somewhat mutually exclusive, where all of that application of radiation to the patient is all in the medical judgment area. It looks like 2 could just be deleted if you accept 1 and 2 as is.

MS. HANEY: There were considerable discussions about that when the working group went through and developed pros and cons for this particular option. The working group did feel that 2 and 3 were in conflict.

We visited that at the last ACMUI meeting. The ACMUI did not believe that they were mutually exclusive.

FACILITATOR CAMERON: Think they said that 2 could be looked at as a finer point for examples of what 3 means.

MS. HANEY: Yes. And I believe that was really their justification for changing the order so that you focused in on the larger one first.

FACILITATOR CAMERON: Okay. Ken?

MR. WANGLER: Ken Wangler from North Dakota.

I don't think that they are mutually exclusive. I think that we traditionally have not gotten involved when the dose to the patient was prescribed by

the physician and administered properly. I think our regulation in the past has dealt with things like administration to the wrong patient, a misadministered dose, the dose was not in line with what the physician had ordered. We have looked at embryo fetus.

So I don't think that they are mutually exclusive at all. I think that when we get into the practice of medicine and we allow the physician to determine the dose to the patient, we have kept our hands off. Our hands have been involved in areas where the administration did not go to the patient as the physician had intended.

FACILITATOR CAMERON: Okay. Let's go to Stuart and then Tom Hill and then to Dr. Carretta.

MR. LEVIN: I just want to share with you an incident that happened ten years ago at a large medical center in Pennsylvania. Apparently the patient got a wrong dose of medicine, and the patient got very ill or died or whatever. So the newspaper reported it in a series of articles on this and discovered that there were no watchdog agency or regulations concerning misadministration of nonradioactive drugs.

And while I was reading the series, I was thinking to myself: Well, if this had been a radioactive drug, the reporter would have discovered that both

Pennsylvania that licenses the norm in a manner assumed were the watchdog agency to help protect patients from this type of a problem. That kind of leads me to what I kind of like in Item 2 on Option 4.

The last half that says, at the very least, we can make sure that the patient gets what's prescribed for them from the doctor without getting into the medical aspects and what the prescriptions should have been in or not should have been.

But generically that last thing regarding the -- it's the last sentence in Number 2, "The physician's prescription is accurately delivered to the" -- I can't read the rest of it -- "to the correct patient." at the very least, I think we should keep that. And it doesn't get us into the practice of medicine.

FACILITATOR CAMERON: So you think that that really helps to explicitly identify the role that the regulator should play.

MR. LEVIN: In my opinion, yes.

FACILITATOR CAMERON: Okay. Well, thank you, sir.

Tom?

MR. HILL: Tom Hill from Georgia.

I'll go back and basically agree with Steve's earlier comment about the Options 1 and 3. I guess I like 3, reversing 3. And that's fine with me.

FACILITATOR CAMERON: Let me just ask a clarification. Steve threw out some numbers, and I wasn't really sure whether he was talking about numbers of options or Statements 1, 2, and 3 within options. So what did you say?

MR. HILL: I understood Steve to say he liked Option 1 or Option 3.

FACILITATOR CAMERON: Is that right? You like 1 or 3? We're going to get into the numbers. I'm fairly confused now.

MR. LEVIN: With Items 2 and 3 being reversed, as recommended by ACMUI?

FACILITATOR CAMERON: That was what's in Option 2.

MR. LEVIN: That was in Option 2 --

MS. HANEY: Yes.

MR. LEVIN: -- where they recommended it, but Steve applied it to 1 and 3, I thought.

FACILITATOR CAMERON: Soon we'll be regulating --

MR. COLLINS: I was talking about Option 2 and Items Number 1, 2, and 3 within Option 2.

FACILITATOR CAMERON: Whatever you meant, Tom agrees with you.

MR. HILL: Okay. Then, I liked Option 3. And as far as taking the item in Option 3 to --

FACILITATOR CAMERON: Would you read Option 3, Cathy, for everybody's benefit? This is the option that Tom is talking about.

MR. HILL: And as far as ACMUI wanted to reverse what was in their recommended Option 2 as 2 and 3.

FACILITATOR CAMERON: Fine with me.

MR. HILL: Reverse Items 2 and 3 in Option 3. Well, maybe that's not the right --

MS. HANEY: Tom, you're looking at the ACMUI recommendation. That's your preferred one; right?

MR. HILL: No. I was talking of Option 3.

FACILITATOR CAMERON: Option 3.

MS. HANEY: Option 3.

MR. HILL: We can just go to Option 3 and forget all the rest of it, period.

MS. HANEY: Okay.

FACILITATOR CAMERON: Okay.

MR. HILL: Now, then, that's my recommendation. That would be mine.

Now, then, I want to stop and back up and address a comment Aubrey made. I want a clarification

from him. Okay? That's on Option Number 2. Is that correct, Aubrey? You may want to go to Option Number 2?

Aubrey, you were talking about the comparable risk. When you were talking about different nuclear medicine therapy-type practices, were you talking about the comparable risks between different types of medical practice, whether it's nuclear medicine or surgery or anesthesia or what?

MR. GODWIN: I was talking about and I believe the ACMUI was also talking about comparing the risks between procedures in nuclear medicine with procedures, say, in surgery, procedures in other medical practices.

And, as you look at that, the acceptable risk is a floating thing depending on the seriousness of the patient and the projected outcomes and various things. I think that's a legitimate thing.

Now, how you apply that in reversing this is recommended. You find out what you're really talking about is mostly in the areas of dose calibrators and perhaps thinking about they have to adopt good QC/QM systems to assure that the physician's prescription is being delivered. That's what really we're looking at.

But what all you include to assure that is to be judged through this kind of concept the way I understood it.

FACILITATOR CAMERON: Okay. We're going to go to Dr. Carretta. Just before we do that to review the bidding, for what it's worth, I have Illinois, California, and Arizona supporting basically Option 2. We have Pennsylvania with Option 4 and Georgia with Option 3, as I said, for what that's worth. But at least we kept track of it.

Dr. Carretta I would note is the President-Elect of the Society of Nuclear Medicine.

DR. CARRETTA: One year removed. Vice President of the Society this year. I'll be president in two more years.

FACILITATOR CAMERON: Okay.

DR. CARRETTA: Although I am Vice President of the Society and I am past President of the American College of Nuclear Physicians, I'd like to speak to this group today only as my primary clinical purpose, which is a full-time nuclear medicine practitioner in a community hospital in a suburb of Sacramento.

And I am very concerned as we look at the reworking Part 35 that what we do in this meeting and other public meetings will set the framework for a final rule, which is in a very fast track mode.

And I'm concerned that there may not be adequate time to do some of the issues that were brought

up earlier in the discussion; i.e., risk assessment on a systematic, well-thought-out basis, and also looking at all of the stakeholders and their concerns with the rewrite of Part 35.

With the medical policy statement, I would agree wholeheartedly with Option Number 3, which is that the NRC will not intrude into the practice of medicine. I think there are mechanisms in place -- I'm sorry. It was the Option 2, Statement 3. I know that Don wanted to change that, but we'll keep this up here.

What I'd like to suggest to you is that there are mechanisms in place in the medical community and in the legal community to handle issues of medical practice.

There are practice guidelines and standards that have been promulgated by specialty societies, such as the Society of Nuclear Medicine or the American College of Radiology. There are procedure-specific guidelines that have been well-thought-out and well-reviewed by specialists in the field of nuclear medicine. And there is the State Board of Medicine that looks at issues relating to the competence or malpractice. And there's also the legal system that's available to patients should there be an untoward event.

So there are issues of patient concerns that are addressed by other groups, either at a state level or

at a national level. And I don't think that the NRC should be involved in this type of practice.

I would also say that when you look at Paragraph Number 2 on Option Number 2, I am not aware of any occasion where there were problems with voluntary standards from the professions, either the profession of nuclear medicine or radiopharmacy.

There are practice certification programs. There are practice accreditation programs. There are opportunities for continuing medical education. I'm a member of the American Board of Nuclear Medicine. And we write the specialty certification exam for physicians who want to be certified in nuclear medicine. It's a rigorous examination period requiring a minimum of three years of training after medical school and internship. So I think there are voluntary groups and voluntary compliances already in place that serve the specialty quite well.

And then the other issue that I'd like to finish up with is that I'd like to speak only for nuclear medicine in terms of the Part 35 revision. I don't want us to be looked at in the same light as radiation oncology or X-ray or other areas of medicine that use radioactive materials, particularly because with diagnostic nuclear medicine, which is probably 95 percent of the nuclear

medicine procedures performed throughout the U.S., there is essentially no risk from diagnostic nuclear medicine.

And then to carry risk one step further, I fly between 250 and 300 thousand miles a year. I probably have more risk for flying that level at that time than any of the patients we will ever see for diagnostic nuclear medicine.

Thank you.

FACILITATOR CAMERON: Thank you, Dr. Carretta.

Terry?

MR. FRAZEE: Terry Frazee, Washington.

We have a very specific state law that prohibits us from making a regulation imposing limits on the ability of physicians to administer radiation to their patients. So in that context, I would say we would have to support Item 3 under Item 2, where NRC or in this state, the State of Washington will not intrude; in fact, cannot intrude into the practice of medicine.

FACILITATOR CAMERON: Thank you. Thank you, Terry.

And this is Dr. Price, I believe. Is that right?

DR. PRICE: David Price from California.

I wanted to consider this scenario. A 60-year-old man comes into the emergency room with chest

pain and undergoes acute tests. He then has perhaps a nuclear medicine valium study. He gets a coronary angiogram. They identify a vessel that's narrow and dilate it with angioplasty. And he goes home feeling fine.

Nobody here would question any of that process. Yet, that patient just got probably 70-rad exposure. Why did nobody question the process? Seventy rads is a lot of radiation. Because there's a very obvious medical benefit. And the medical benefit far outweighs the risk of 70 rads or whatever, 50, 60, 70, 80.

So what are we talking about here? What we're talking about here are situations not where the risk is great and the benefit is minimal, but we're talking about situations where the NRC is trying to make a decision as to whether the risk or the injury, quote, "was greater than any potential benefit."

Any situation in which that is the structure that's being imposed is requiring the NRC to make a medical judgment. That should not be put into place.

The NRC cannot set up the mechanisms to evaluate medical risks and benefits. And even if we're talking about very small medical risks and benefits, it's still putting upon the NRC the requirement to make that decision. They don't have that expertise, and there are

many other mechanisms in place for quality control, quality assurance of medical practice.

The issue of the wrong patient being injected, for example, in our hospital, that's an adverse event. It gets reported to our hospital system as an adverse event. It gets assessed locally. It gets reported to all the various regulatory agencies involved in that type of an adverse event.

The NRC should not be required to have a structure that makes some sort of a medical judgment or medical benefit. The only way to put that in place is to completely take regulations out of anything related to medical practice. I think that's what should be done, that medical practice should not be regulated by NRC regulations.

FACILITATOR CAMERON: Dr. Price, while you're up there, I know that you, like everybody else, is suffering from the disadvantage on this particular one of not having all of this in front of you, but is there one of these options that you saw that would bring that point home very clearly in the medical policy statement?

DR. PRICE: You know, in what I've seen, everywhere I see bits and pieces of it. All I can say is that there should not be any regulations that are duplication of regulations intruding into the medical

practice area. In other words, there are already mechanisms in place to quality control medical practice, including training regulations and quality assurance regulations.

So I really don't think the NRC involves in an oversight of the medical practice.

FACILITATOR CAMERON: Okay. I think that that can be sorted out, but I think you also raised an important underlying issue. Say that we have this handy, dandy medical policy statement that we choose.

How do we ensure that the regulations and the implementation or enforcement of the regulations are consistent with whatever policy statement we have? I think that's another issue.

We're moving towards break time, but let's go to -- is it Roland? Roland, you have your card up. Roland and then Aubrey and Don Flater and try to close things out on the break here. Roland?

MR. FLETCHER: Roland Fletcher, Maryland.

I find myself not being totally sure of what answers we're really developing to the question that was originally asked about risk. From my perspective, I'm not interested in intruding in medical judgments. I'm not interested in interfering with the doctor-patient relationship.

What I am interested in is ensuring that the procedures for radiation safety are being followed by all medical personnel. That includes the physician. And when they're not, then I need to make sure that by my following the procedures, someone isn't exposed more than they should have been.

I don't feel that that is intruding into the practice of medicine. I feel that that is my job as a regulator to protect. And I believe and I've had situations where there have been repeated instances where simple radiation safety practices were not followed and there was no physician oversight, even though the procedure required physician presence. That's what I'm interested in.

FACILITATOR CAMERON: Let me ask you one question on that that will focus things a little bit for me. Do you think that the existing Part 35 goes beyond your concern?

MR. FLETCHER: Well, I must admit that I find existing Part 35 to be very prescriptive. And I've worked on the workshop adequacy and compatibility. And we made some recommendations on how that can be changed from a compatibility perspective.

I'm not sure. And I need time to study the various options to see which one that I would really select.

FACILITATOR CAMERON: Okay. I guess the point is that you might make a statement. Everybody might agree with the statement like Roland's. But in terms of what the regulations should be to implement that, I guess that's where we get into the debate.

At any rate, Aubrey, Don Flater, and Ruth. Then we're going to take a break. Aubrey? Oh, and David. I'm sorry. You had your card up for a while.

MR. GODWIN: It seems to me that one of the things and probably the only thing that we've really talked about as far as the regulatory agency is that we're to assure that the prescription is delivered as described by the physicians, whether it's an X-ray, whether it's in particle accelerators, or whether it is in nuclear medicine.

In X-ray, we certainly check the equipment to make sure that it's operating within certain parameters, that it doesn't deliver doses all over the wall, for example, when they make a chest X-ray. Particularly in mammography, we look at the quality control of the dark room.

We look at a whole slew of things. But they're all geared toward making sure that what the physician wanted, he gets and gets a quality product. We try to set up a minimized scatter so that the X-ray film comes in with a minimum of volume so he can read it or she can read it better.

Particle accelerators, again, we try to make sure that they don't create an adverse problem outside the facility but also that they do, in fact, have it calibrated and things so that they can deliver that therapy dose. I think that's what we're looking at with radioactive material.

But there is a little caveat I'd throw in. One of the issues that really hasn't been addressed anywhere so far is: How do we view the role of a nuclear medicine physician? I think your perception of what role they're going to play in the process colors how you interpret what we need to do as regulators.

If you view them as I traditionally view the therapist type, a very key part very carefully of working through the patients' files and determining what procedures should be followed, determining what dose should be delivered, and becoming, if you would, essentially a prime physician care-giver. Then that's a very important role. If you do that carrying over into

the diagnostic area, then you get a very different answer for what they should be doing.

Then you look at it as perhaps what I call the pathologist's view, where you go in and give some blood and you never see a physician, you don't know whether a physician's ever read anything.

I think that we really need to hear from the nuclear medicine community on how they view themselves and how important it is in dealing in these things. I would like to see some minimum physician involvement, even the diagnostic test, because let's face it. They're the only ones who have had the training to know how to select the patient, prescribe the dose, and interpret the results.

Now, granted, the doses are low. And you may be well to let essentially a physician who is licensed to practice medicine order up a test. I don't have a whole lot of problem with that, on whether there's a real low dose involved.

But somewhere in there, there should be some competent assessment of persons that we know are qualified who have really been trained to look at these things to determine that this is appropriate interpretation, at least, of that test.

That's where I see the diagnostic nuclear medicine position being evolved and who should be the

authorized user and who should be the one reading the test. Others can read them if they want to, but I just really think we need to assess what is the role of the nuclear medicine physician both in the diagnostic arena and the therapeutic arena.

Thank you.

FACILITATOR CAMERON: Okay. Thanks, Aubrey. We may put a finer point on that later.

David?

MR. SNELLINGS: Yes. Just in the interest of time, Aubrey said basically what I was thinking here. The physician is responsible for what happens and what fails to happen.

And where I see a breakdown, certainly we should not practice medicine. We should not get into the medical judgments and such. But under Option 4, it talks about to make sure that it is delivered properly.

I think here is a real concern that we have seen in our state recently that the prescription was not accurately delivered to the correct patient. You know, to me that's a breakdown in the process that the physician is certainly responsible for. Hence, is that an indicator of that involvement? I think these physicians should definitely be involved in this process.

FACILITATOR CAMERON: Okay. This may be a great option. But then the question is: How do you act on that?

MR. SNELLINGS: Yes. I like Option Number 2, but I also like that specific mention of the physician's role in making sure that it is accurately delivered.

FACILITATOR CAMERON: Okay. Thank you.

Don?

MR. FLATER: I appreciated Dr. Carretta's comments, but I also have a great deal of problem with it because he didn't take it the one step further. And that is getting the medical boards, dental boards, whomever to actually open up and take some action against some physicians.

It may not be the experience here in California, but at least the experience in the State of Iowa is they are good old boys' and girls' groups. And they don't necessarily want to go after one of their own kind.

So we have a great deal of trouble if we have somebody doing something improper. I have no problem with those people taking care of them, but they won't do it. And so we have a real problem from there.

The other issue relative to qualifications, I would dearly love to be able to put in that they have to

be a Board-certified whatever to practice, but when your attorney general turns to you and says you can't do that because that is promoting a private organization to do it, we sort of get our hands tied.

And that's where I think it's so important for us to sit down and establish a training standard that everybody has to meet for the area that they're going to specialize in. And we have to keep that.

But using the Board of Medical Examiners, I would submit, at least in the State of Iowa, is a very shaky thing to try to do because everybody on the board is an M.D. and he doesn't want to have anything to do with going after one of his own kind. It's a good old boys' group, good old girls' group.

FACILITATOR CAMERON: Thank you, Don. That's an important point.

We're going to have to break right after Ruth because the coffee lady is going to disappear. And if I can't keep us on time, at least the coffee lady will. Ruth?

MS. McBURNEY: I agree that we should not get into the areas including medical judgment. However, if we are doing a paradigm shift away from any type of patient risk to the patient and more in the occupational and

public radiation safety area and that is the basis, this policy forms the basis for the rulemaking.

Where that really comes into play is on the training and experience -- we've been through a lot of this in our state in looking at this -- and diagnostic nuclear medicine is truly low-risk.

Then putting more prescriptive requirements, such as Board certifications and so forth, on there will not fit in with the changes in the medical policy because the focus is now on radiation safety. And so there would be radiation safety training requirements and some minimal training in administration of radiopharmaceuticals to humans.

I'm speaking mainly in the diagnostic areas. But just keep that in mind, and there will be more of that when you get to training.

FACILITATOR CAMERON: Thank you. Thank you, Ruth.

Steve and Aaron, I would just ask you to see if you can work your comments in in another discussion that we're going to have. I think that we really took some time here because we're dealing with basic underlying concepts. Let's be back at 20 to 11:00. And we're going to go right into the radiation safety committee area.

(Whereupon, the foregoing matter went off the record briefly.)

FACILITATOR CAMERON: Before we get to the cross-cutting issues, there was a proposal that some of the states had in regard to the policy statement. Unfortunately, here we're not going to have time to get into the discussion of it, but it captures a lot of the previous discussion.

When we get to the workshops in Chicago and Philadelphia, we'll be able to be a lot more systematic and spend more time here. But I'm going to ask Steve to read us a proposal on the policy statement that Steve and I think Aaron Padgett, Aubrey, a number of states who have seen it seem supportive.

What can we put up for you, Steve, that would be useful for people in terms of explaining this?

MR. COLLINS: Option 2.

FACILITATOR CAMERON: Option 2? Great. Well, this is not going to work.

(Laughter.)

MS. HANEY: I have it that way. Do you want it that way?

FACILITATOR CAMERON: No. I'll put the General Counsel on the same side as the technical community.

MR. COLLINS: What we think captures the essence of all of the comments that the states at least were making and some of those from the medical community would be to take Option 2 and remove the last sentence of Item 2 and replace it with the last sentence of Item 2 in Option 4, --

MS. HANEY: The one that states in --

MR. COLLINS: -- "Make sure the physician's prescription is accurately delivered to the correct patient." Put that sentence the last sentence in Item 2. Replace the last sentence of Item 2 in Option 2 with that sentence. Go back to Option 2 now. That sentence is a reference to comparable risk and other modes and types of medical practice.

FACILITATOR CAMERON: I wanted to get that onto the transcript. And possibly sometime this afternoon, I don't know if we can have a typed version of that for people who want to look at it, but we'll at least try.

Cathy, do you want to take us into the, what, radiation safety committee?

MS. HANEY: Yes.

FACILITATOR CAMERON: Okay.

MS. HANEY: All right. This particular slide you do have copies of. Now we'll kick into what was

handed out this morning. These are the options that the working group developed as far as the radiation safety committee goes.

Item Number 1 is "Status quo." Under the status quo, just to pick up a couple of things out of the rule, a radiation safety committee is required for all uses of radioactive material in the medical setting.

The committee is used to reviews a lot of programs, to do annual reviews of the radiation safety program. It's used as a mechanism for approving authorized users, authorized nuclear pharmacists, radiation safety officers. It's also used to review dosimetry reports and to review incidents.

The working group was looking at pros and cons of keeping status quo. And one of the strengths that came out of that is that the committee by having the requirement, it really forces or if you want to use the word "force," but it requires communication between the disciplines within the facility.

Now, we recognize that the current rule is rather prescriptive. It tells you who has to be on the committee, how many times you have to meet, how often you have to get the minutes out.

If we stay with the status quo, it doesn't mean we would have to keep the rule language as it is

right now but just the concept that a committee would be required for all uses.

We also recognize that this really is not a risk-based requirement in that there are some facilities where they're only practicing diagnostic nuclear medicine. There's only one physician. And is it really required that there be a committee at this type of level?

Out of Option 2 or Alternative 2 up there is that a radiation safety committee is required for medical institutions and only for those where what we're saying very loosely right now the higher-risk modalities. In other words, if you only had diagnostic nuclear medicine at a facility, a radiation safety committee would not be required. It's meant to address those with the higher risks.

Now, one thing that came out at the ACMUI when we discussed this -- and I want to make this clarification here also -- is that this doesn't mean that if you have a facility that has all six modalities that your radiation safety committee would only cover for high-risk. The intent would be that you would also discuss the uses at the lower-risk procedures.

Option 3 is that radiation safety committees won't be required for anyone. It would come completely out of the regulations.

And the last one up there is that the radiation safety committee as such would not be required. However, we would ask that medical licensees establish and implement a program for administrative and technical oversight of the radiation safety committee.

This would give the licensee some latitude and authority in how they want to manage their program thinking about if we chose this way, how would the rule language go. What sort of things would we say in there that fall under oversight of the radiation safety?

This program would have to address things like approving the authorized user, reviewing incidents, reviewing radiation safety procedures, and putting in some type of mechanism for the interdepartmental, interdisciplinary communication between the different types of modalities.

So I think that's all I'm going to say as far as an introduction. I think we've king got a wide area here from no radiation safety committee to status quo, where everyone needs it. And I'll just turn it back to Chip at this point.

FACILITATOR CAMERON: Okay. Thanks, Cathy.

I guess I would ask. As Cathy mentioned, there is a wide range of options here. I would ask you, in addition to looking at these specific options, are

there any options that were missed here, anything that could profitably be put up there? I'm going to go to Ed Bailey first.

MR. BAILEY: I've probably got some rambling thoughts, but I can remember back to the days when in the agreement state I worked in, we did not require committees except at broad license facilities. And we tried, then, later on to, particularly among those broad license facilities, make sure that this radiation safety committee included radiology.

I know NRC would have some difficulties with maybe requiring that there be a radiologist on this committee, but when we look at facilities, major hospitals and so forth, or even the small community hospitals, there's usually somebody who can spell radiation over in radiology. We don't do it in California, but I wish we did, that we required the radiation safety committee to include X-ray.

So I guess I'd have some difficulty with having the committee. I see the benefits of the committee in that you essentially don't have a one person running the program and if that one person happens to be not sterling, that there's no review of that program or what they're doing.

I guess I have to look at Number 2 as being a preferred option, but I think certainly as we as agreement states begin to look at how we would look at a radiation safety committee, I think it's sort of ludicrous that we don't as an agreement state regulating both X-ray and whatever else we're talking about, nuclear medicine, that we don't require that they be as involved in the radiation safety efforts of the hospital as we require the nuclear medicine people to be involved.

I would guess -- and I don't know -- that far more often X-ray studies are repeated, as opposed to nuclear medicine procedures. And the disadvantage, of course, there is patently obvious that in order to redo an X-ray procedure, you've got to give them another dose of radiation; whereas, in nuclear medicine, that may not necessarily be true. You may be able simply to recount them or something.

FACILITATOR CAMERON: Okay. Thanks, Ed. That was support for Option 2, but perhaps a more important point is an admonition to agreement states to add a requirement that if there is a radiation safety committee for purposes of AEA materials, that it also include non-AEA material coverage, which would seem to make sense.

Bob?

MR. QUILLEN: My thoughts were very similar to Ed's, and I just wanted to emphasize the issue of the broad-scope license facility, where I think a radiation safety committee is absolutely necessary. And that's not reflected up here in the various options where facility is a broad-scope licensee.

FACILITATOR CAMERON: Okay. Is it Ruth or John that has their --

MS. McBURNEY: Ruth.

FACILITATOR CAMERON: It's Ruth. Okay.

MS. McBURNEY: I would support the Option 2. I think that we have a lot of small facilities that only have one physician and he's more on a route around several. And to have to have a radiation safety committee for diagnostic only probably doesn't serve much of a purpose, especially if the more prescriptive rules stayed in there on how often they had to meet and who had to be on it.

So I would support the Option 2 and also take a look at the requirements themselves on sort of backing off from prescribing the number of times they have to meet in taking the minutes or all the things that are covered in the current rule.

FACILITATOR CAMERON: Okay. Thanks, Ruth.

How about you, Aaron?

MR. PADGETT: I think Option 2 comes closer to what my experience says is needed than any other. However, I would take out the exception because, even with the diagnostic, our experience is that the programs get screwed up and they end up giving the dose to the wrong patient and things end up in places that they shouldn't. The radiation safety committee is not functioning very well. So I would not put an exception in there for the diagnostic.

I do agree with the comments made earlier about the individual physician office.

FACILITATOR CAMERON: What are the concerns that people might have with Alternative 4? Ruth?

MS. McBURNEY: I think Alternative 4 would require that licensing staff make a judgment call on: Is this acceptable? Is this not acceptable? It would probably be more time-intensive unless you did set up the criteria.

If you did set up the criteria, that would need to be in the rule. So you would probably wind up with something that would look like some sort of requirement like in Option 2.

FACILITATOR CAMERON: It may sound like a good idea, but, in actuality, it may be simpler and as

effective to just have a radiation safety committee in Option Number 2.

Ed Bailey?

MR. BAILEY: I'm going to be a good regulator in the sense of good regulator being a good bureaucrat, sort of an oxymoron.

I see Number 4 as having some problems, much as Ruth mentioned. I would rather see that the Committee be required with then the suggestion in the regulations that, hey, it may not be necessary if you can demonstrate you don't need one, as opposed to the other way around, where the regulatory agency has to justify why you need one. Now, the regulated community won't like that approach as much as the other way because it's not as clear-cut on our side.

I didn't really understand Number 4 there when we were first reading it. I guess, even after discussing it, though, I still think that Number 2 is a better way to go. And I guess I would expand the exception to include possibilities for other things, other than that, such as a single user hospital or the circuit rider or whatever.

Somebody made a comment, though, -- and this is a different subject -- about there was a committee needed when physicians were allowed to be trained in a hospital. I hope that we are far enough along that we are

not still allowing a physician to hire somebody and bring them in and preceptor them when they haven't had the didactic and academic and clinical training in a formal program.

I think Texas has addressed this somewhat in requiring that that big string of initials be approved in the medical training. I think we have had more problems where we have allowed an individual physician to bring in a partner or an associate and then provide the training for that individual than we have where people have gone through an approved program.

FACILITATOR CAMERON: Okay. Your idea of the regulator bearing the burden if one should be required would at least require the regulator to state: What are the objectives? What problems are you trying to address through the formation of a committee? And I think that's always a good idea to try to lay those out in terms of a reality check.

Don?

DR. COOL: A clarification and then a question for everyone. I think when the option was put together and any time you try to write it in a sort of shorthand form, you lose a lot of what goes into hours of discussion at several different levels. Was the thought that, in fact, the rule here would, as Chip just laid out, lay out

the key objectives that would have to be achieved by whatever oversight mechanism?

And we're all used to saying this is a committee. And maybe the committee is the right kind of approach, just to help people understand what I think was underlying some of that issue.

Now, the question that I have is one of the age-old regulatory questions as to what extent you just go ahead and say it in the rule and be done with it. Around the Commission, the word "exemption," which was sort of where you would end up for alternatives, is a very bad word of late, trying not to do things by exemption too often.

So the question I would ask is: If the group believes that it's better to put the requirements into the rule, how many times do you think -- and this is one which the medical community might also be able to give us feedback on -- how many times would there be a need for an exemption to some different kind of approach or does this all end up being simpler for everyone?

If we're talking low numbers, ones, twos, threes, then I would certainly agree with you. If we're talking 20s, 30s, 50s, then we might be shooting ourselves in order to have hold of the gun or something like that.

So that's the question as to how many times an alternative strategy might be useful or might be needed.

FACILITATOR CAMERON: Okay. Thanks, Don.

With Don's question in mind, let's go to Cathy Allen from Illinois and then go and ask some advice from the medical community on this issue.

MS. ALLEN: Don, I'm glad that you clarified that. I think that if you want to approach something like an Option 4, that you have to be very clear in the rules about what kind of performance standards you want to hold your life and seas to.

But I'm also concerned that there's a feeling among the regulatory agencies that we would then be compelled to write a guidance document that would tell licensees exactly how to implement this. And that's exactly what everybody doesn't want to do, regulate by guidance.

So I appreciate the effort, but I just want to relay that bit of warning.

FACILITATOR CAMERON: Good. I guess we're getting some of the disadvantages out on the table for Option 4.

Terry?

MR. FRAZEE: Terry Frazee from Washington.

I guess I'll speak in favor of having guidance. In many respects, it's a lot easier for the licensee or the license applicant to have something that they can just take and implement, whether it's a rule or whether it's guidance or in our state, it's the license application. We have a license application. If you like it, sign it. You're done. You've got the license in your hand. And it's a very quick process.

It used to be that we had NRC rules that were more general and there was the reg guide. And it was very prescriptive. There was only one way to do it, but at least it was there.

It is unfortunate that it became sorted into the regulations. And that's been part of our problem for the past few years, is that prescriptive element getting in there. It's been useful for some licensees, and it's been less than useful for others.

If we could get back to the Number 4 situation, where you have a performance-based rule, and leave it up to the state or the NRC to come up with an acceptable alternative, such as in guidance or standard application form or whatever, that would sort of get us down the road that it would be very easy for the majority of applicants to say, "Hey, great. The standard application form, the reg guide, so to speak, I can live

with that. Give me the license. Hold me to that. It's fine."

For other physicians who want to create something different, okay. It's going to take a little bit longer for us to go through the review process, but that's their choice. And it can be done. It can be worked out that way. We do that infrequently in the State of Washington because most of them really appreciate having the standard application to be the reg guide.

So from that standpoint, putting together everything that has been said, yes, it's problematical for us to have to go back and look at those alternative approaches, but that's a lot easier than the constant hassle that we would have if there weren't some sort of guidance to compare it to.

FACILITATOR CAMERON: Okay. Thanks, Terry. This is point/counterpoint.

I see it's Dr. Price; right? Okay.

DR. PRICE: It's David Price, San Francisco. I'm a member of our RSC and a former chairman. My view of the purpose of the RSC is it allows the local institution to practice nuclear medicine, to carry on research, and so on, with a minimum requirement for the state agency or the NRC to be involved with the small details. They simply have broad oversight.

So, really, the role of the RSC is determined by what the federal regulations are. And I would think the solution is between Number 1 and Number 2 depending upon where we end up the overall changes in Part 35.

But what you want is to have sufficient autonomy within the radiation safety committee that the institution can run well, whether it's research or clinical, and that there's a minimum of requirement to go to the state agency or the NRC on anything other than a very broad oversight basis.

That also means that you don't need a lot of detail and guidance. What you have is the regulations.

FACILITATOR CAMERON: So you're suggesting that the intent of a performance-based regulation may be met by simply requiring a radiation safety committee and then letting the institution sort of use that to cut through a lot of or avoid a lot of bureaucratic red tape, I guess? Is that?

DR. PRICE: Yes, local management. And then you have the oversight of the state or federal agency when there are site visits and reviews and whatnot or if there are problems that need to be reported back.

FACILITATOR CAMERON: Okay. Thank you.

DR. COOL: If I could ask one other clarification of you, Dr. Price, because I think we have

jumped issues just a moment. I might as well finish this off. If I understood you correctly, one of the key advantages to having a committee would be to make small adjustments, changes, allowances within the program.

In NRC land, where the reactors still have most of the resources and otherwise, that has an acronym like everything else. It goes by 50.59, which is the part of the regulation for reactors which allows them to make certain changes there within the standard assessed scope and doesn't change safety.

Is that what you're advocating as a useful item because that presently has only very limited, if at all, within any of the materials areas?

DR. PRICE: Again, I have no experience with the reactor side of it, but I think you want to maximize the ability for local operation and minimize the need to go back to state or federal agencies except where either there are major problems or there's a regular, as I say, site review or oversight mechanism?

MR. BAILEY: Can I make one thing?

FACILITATOR CAMERON: Do you have a short clarification, --

MR. BAILEY: Yes.

FACILITATOR CAMERON: -- Ed, before we go to Dr. Carretta?

MR. BAILEY: Yes. Dr. Price is at a broad-scope facility. His radiation safety committee has a little more power and authority, although he does have the largest broad-scope license in terms of conditions. It has, what, 129 now? So I think there may be a slight difference in his facility with an RSC and one at a local hospital. And Dr. Carretta may address that.

DR. CARRETTA: Well, I was just going to bring that. Even though we're in an enlightened state such as California, we still have to deal with some of the regulatory issues.

One of the problems with a radiation safety committee as it is under the status quo is it's very prescriptive and tells us not only who must be on it, how often we should meet, when our minutes have to be transcribed and available, when we have to do our ALARA review.

I mean, there are significant onerous regulations for a small community hospital or a private outpatient office that handles nuclear medicine. So I would favor something other than the status quo unless the status quo was considerably changed to a risk, performance-based status quo.

I think a combination of Number 2 or Number 2 and Number 4 depending upon what you call this entity

because I don't think you need to call it a radiation safety committee -- you could call it whatever you want, but the functions would be similar to a traditional radiation safety committee.

And I think for the small community facilities to have more leeway, more individual variation in what we do -- for example, you may want to put in something that says the radiation safety committee or its designate, whatever it becomes, would meet a minimum of every six months.

And then if you needed to meet more frequently or if there was a problem identified, nothing would prevent you from meeting quarterly or monthly or daily if you needed to.

But to tell me that in a 150-bed hospital, that I have to meet 4 times a year without giving me any rationale as to why I have to do that, it doesn't make a lot of sense.

And it's very costly to do this type of meeting. It's time-intensive, it's labor-intensive, and it takes people away from their primary health care duties to sit in a room to cross a line and check an item on a license application.

FACILITATOR CAMERON: So I guess you're going back to what Ruth said at the beginning. You might have a

very simple requirement that said there should be a radiation safety committee and the objectives or the functions of that committee should be such and such. And then you leave it up to the institution in terms of how they're going to implement that particular requirement.

Carol, we'll go to you just right after Aubrey. Aubrey?

MR. GODWIN: I think a key point needs to be raised at this point as: What is the anticipated compatibility level for this because the degree of flexibility a state might have might be important as to how strong we want to go on this thing?

I believe currently it's a C level, and that means that we can be a little more flexible than we used to could. I think that's just been changed.

FACILITATOR CAMERON: An agreement state might be for a particular option or against a particular option depending on how much flexibility they had with that option?

MR. GODWIN: That's right.

FACILITATOR CAMERON: Does that make sense?

MR. GODWIN: Do you have a feel for that now?

DR. COOL: Well, without tieing any of the hands down as it goes through the process, I guess I would have hoped that this kind of thing could be C, where the

objective of click, click, click, the three or four things that you wanted to do, would be the way we would look at that because that would be more in keeping with where at least I know some within this debate would have wanted to go in terms of being in more performance orientation and having the rule state the objectives to begin with. And then stating the objectives your way, we're still looking at objectives.

The closer we get to a more prescriptive approach of saying, "You must have something which is actually titled 'RSC,' even if you then have a lot of flexibility within some of the other details," I would guess we'd still be probably somewhere in that range.

FACILITATOR CAMERON: Okay. Let's go to Dr. Marcus, and then let's go to a relatively noncontroversial issue: the quality management.

(Laughter.)

FACILITATOR CAMERON: Carol, would you like to finish this up?

DR. MARCUS: I think most people have the right idea about loosening up on what's actually required. First of all, I don't think radiation safety is a legitimate concern in any medical institution where the physicians are qualified to begin with.

We're not really talking about radiation safety. We're talking about radiation management perhaps. In the broad licensed institutions in which I have worked and in whose committees I sit or have sat, the main thing we do is look at research projects, look at the radiation dose to human subjects from research, the research end.

The radiation safety officer and his staff take care of making sure the film badge readings are within reasonable limits. Basically they're the Part 20 committee, in essence. And the committee itself doesn't even bother with that.

You could imagine a situation where an institutional review board, which is required by the Department of Health and Human Services, puts some people on there who understand radiation so that they take care of the research use of radiation when you're looking at the whole picture of research projects in an institution so that the function is there, but it may not be in the same committee that looks at Part 20-type items. And that's why I favor Number 4.

I think a lot of people will have a radiation safety committee, but right now we have a lot of redundancy. We have a radioactive drug research committee because of the FDA regulations that is absolutely duplicative with part of what the radiation safety

committee does, which isn't necessary. You have an institutional review board, which duplicates often some of the work that the radiation safety people do.

You waste a lot of people's time. And if you have something like 4, then an institution can decide how to best use people's time and minimize the redundancy but still get done what you need.

FACILITATOR CAMERON: Okay. Thank you, Carol.

Cathy, would you like to put the quality management options up? I'd like to see if we could finish this and then go to lunch. And then we'll come back and take the other items.

MS. HANEY: Here are the options for the quality management program. I think it's important to keep in mind on this one that we have to go back to the SRM direction that said we should look at the quality management program and we should focus in on three things, their: confirming patient identity, requiring written prescriptions, and verifying dose. So that's really as far as the working group goes our ground zero.

The options. Number one is status quo. And that's just a quick overview. There are five objectives. Audits are required. You need to retain written directives and records of administered doses. You need to

submit a quality management program to NRC, changes to the program. And you need to maintain recordable events.

Looking at our options, Number 2 is to only require a written quality management program. What we're looking at with this item is a quality management program that would address the three issues that the SRM said. In other words, this isn't the current A from the current 35.

Option 3 is to require a written quality management program, again the same one that you're looking at under 2 but to add onto it retaining the written directives and a record of the dosage and performing audits.

And then the fourth one is where we have deleted the audit function. But under this one, you're maintaining a record of recordable events. I'd like to mention also here that recordable events will come up this afternoon when we start talking about the thresholds for reporting to NRC.

So there is a question about whether we would even retain recordable events. And whatever we do in one area obviously has to flow through to the other areas. So the issue of the threshold for recordable and whether we have it or not will be revisited under another subject that we discuss later.

That's just a quick overview, and I'll turn it back to Chip.

FACILITATOR CAMERON: Okay. Again, four options. Do we have all of the options up there? We may not. I think that there will be some. I think we will hear some comment on that. So, again, think about that. Do we have all of the options identified? Who would like? Aubrey, are you going to start on this one?

MR. GODWIN: I would like to ask a few clarifying questions. For example, under 2 and perhaps 3 and 4, are these written quality management programs to be submitted with the application or are these something that they just have and the inspectors review it? I would like a little clarification of that.

MS. HANEY: At this point, this is strictly a working group answer to that, that it would be something that would stay at the hospital level and the inspectors would look at it when they came out. It would not be something that came into NRC for review.

MR. GODWIN: Well, if that's the way it's run, I would view that that's a trap to cite the facility because they really don't know whether they have an adequate program until the inspector gets out there and tells them it's wrong.

I would prefer if you're going to have a written quality management program, that it at least gets submitted and reviewed and the agency is committed to at least the concepts that are in it so that they can't be blind-sided and inspect it and cite it.

Having said that, I would like to leave it as liberal as we could and go with something like Number 2 that just calls for the objectives that they're to address with it, rather than it being very prescriptive. As I recall, the current rule is fairly prescriptive about things.

FACILITATOR CAMERON: Does Number 2 in the mind of the working group do what Aubrey is suggesting --

MS. HANEY: Yes.

FACILITATOR CAMERON: -- or is it a different concept?

MS. HANEY: No. It's the same concept. When looking at how we would write ruling, which for 2 it would be basically just the licensee would need to have a written quality management program and that program would need to make sure that identity is confirmed, written prescriptions are required, and that doses are verified. And it would be a period.

Another change that we thought about in this particular area is that the criteria for a written

directive would also change. And currently the requirement for a written directive is very prescriptive. It says if you're doing this type of therapy, you need to have a written directive. If you're doing something else -- you know, under each type of the modality, there's a requirement.

The working group was looking at making it a dose base. We to a certain extent pulled 50 rem out and said that if it's possible, that a written directive would be required if the dose to an organ could exceed 50 rem, whether 50 rem is the right number or not. We're certainly open to it changing, but the key here is that we were not looking at having a specific requirement for written directive for each type of modality it would be taking into a dose base.

So the long answer to your question is I think we're where Aubrey said.

FACILITATOR CAMERON: Okay. Good. And for those of you who might be anxious because of the option to eliminate the quality management program, it isn't there. We will be discussing that. And I think that discission should center on why that there should be no or, however it would be phrased, why there should be no quality management program, why there isn't a need. And I don't know if anybody is going to suggest it here.

Steve?

MR. COLLINS: Steve Collins from Illinois.

It's my understanding after the discussion of Item 2 up there that that very closely matches with the alternative version that the SRCR working group had come up with for a model state regulation that applies to --

FACILITATOR CAMERON: Can you say who the --

MR. COLLINS: I would like to confirm with Bill Passetti if that is an accurate statement.

FACILITATOR CAMERON: Could you just explain who --

MR. COLLINS: David Walter. I'm sorry. David Walter, the current chair of that group.

FACILITATOR CAMERON: Could you state what the acronym stands for, who that is, what you're talking about there with that one?

MR. COLLINS: What I'm talking about is the conference of program directors' group that's responsible for developing for all of the states' use as they see fit a model medical radiation regulatory set of rules.

FACILITATOR CAMERON: Okay.

MR. COLLINS: And currently David Walter I think is the chair of that group. And Terry Frazee is a past chair. So I was hoping one of them might be able to tell me if, in fact, that alternative version, the one

that would not make states compatible with NRC's current rule. Does it match closely with Item 2?

FACILITATOR CAMERON: David?

MR. WALTER: David Walter from Alabama.

To a certain extent, that's true. I think, though, that the current one that did not get concurrence that made us get withholding of a concurrence from the NRC actually went a little bit further than what our intent was on this. This backs off even further from what we had originally placed in the current suggested state regulations for Part G.

FACILITATOR CAMERON: So it's less prescriptive when you say, "backs off further"?

MR. WALTER: Yes. And it's extremely close to what we have right now in Part G. You'll see in the new Part G that's going to be coming out in the very near future or will be going to the executive committee that what we have done is tried to make a document that can gain concurrence and that also would allow a state to adopt a program that would be compatible.

But what we did is we placed a number of items in that section in brackets and said that if you want to be compatible, you've got to adopt this bracketed text. If you don't adopt the bracketed text, you will not be gaining compatibility with the NRC as it currently stands.

But we don't necessarily agree with it. And so because of that, we don't say you should go that far. We don't recommend that you go that far unless you need compatibility.

(Laughter.)

FACILITATOR CAMERON: Can we make sure that when we get to the workshops that we have a copy of that proposal with us in case it is brought up at the meeting?

Okay. Steve, that answers your question, I take it.

MR. COLLINS: Yes.

FACILITATOR CAMERON: I see David has his card up, but it's not David. So just introduce yourself.

MR. THOMPSON: Jared Thompson with the Arkansas Department of Health.

I think the important thing we have to remember on this is it doesn't matter how prescriptive this is. It's not always going to work. We have a classic example of a facility who had an ideal quality management plan. They also had ideal misadministrations, bad misadministrations. The hospital fixed the problem real simply. They suspended the doctor's privilege to do that.

I think that's where the responsibility for quality management is. It's not with us as an agency or

as a regulatory agency, anyway, to tell a facility how they're supposed to do their treatment plans and how they're supposed to follow procedures.

I think the status quo is very prescriptive. And we've got to back off on some of this regulatory mess that's been made in a way because it has become regulatory burdensome to some facilities, particularly small facilities that are just trying to serve the community in which they serve.

Ideally, if you're going to have to have something, Number 2 is the best option. Let's let the hospital manage this, not us.

FACILITATOR CAMERON: Okay. Thank you.

But I think you would be espousing what I think we're going to be calling Option 5, which is no quality management program and build quality in through some other mechanism. Okay. Thank you.

Ed?

MR. BAILEY: Bailey from California.

Number one, get rid of the words "quality management." It's a red flag sort of to the bulls in the audience and at this table.

FACILITATOR CAMERON: I don't know if anybody takes offense at that, but --

MR. BAILEY: The "quality management" tag for many of us represents a bad history. Give it a new name.

FACILITATOR CAMERON: So that the --

MR. BAILEY: Then I could be more rational in how I respond to it. But I think there is a Number 5 option. And I would comment on some of the elements in here.

I think it's important that you have a quality program, but, as I looked at this in the beginning, I saw written, written, written. And somebody will obviously correct me because I'll be wrong, but most of the misadministrations that I'm aware of did not occur because there was a misunderstanding in an oral prescription given to someone that occurred because doctors don't write well or people don't read well.

And they end up giving millicuries, instead of microcuries. Those are the ones that I'm familiar with that have happened. And, in fact, I can't sometimes tell the difference between a micro and a milli depending upon who wrote it.

So I think in California, the definition of a prescription starts out an oral or a written directive. And so the first words there are oral. Quite often, that's the way the patient is referred by phone to

somebody, "I'm sending somebody over for a scan. I want this, that, or the other done."

And hopefully the nuclear medicine physician has directives within their department that describe under what conditions you can take a referral and from whom you can take a referral.

I mean, if Ed Bailey phoned up and said, "I'm sending over Girard to get a brain scan," I hope somebody would question that.

FACILITATOR CAMERON: I guess that depends on how much you know about Girard.

(Laughter.)

FACILITATOR CAMERON: And I wouldn't take too lightly the point either about the fact that the words "quality management plan" can have such a negative connotation at this point that you may be in the hole no matter what you try to do with it.

Cathy, do you want to --

MS. HANEY: Yes. I'd just like to say we have recognized that quality management is a red flag. So we're very open to the name a regulation contest. So if this group wants to provide some names, that would also be very helpful.

FACILITATOR CAMERON: Okay. Gentleman from Alabama, I believe.

MR. McNEES: I'm Jim McNees from Alabama.

To give a little perspective on it, if we're trying to prevent I guess what NRC used to call diagnostic administration, we still keep a record of them and have them report them.

Looking at a compilation of many years of that, we found that 50 percent of the I guess reportable events now, what NRC used to call diagnostic administrations, resulted from the technician reaching over here and picking up the wrong syringe. It was not the syringe that they intended to give this person. That was 50 percent of them.

Forty-nine percent of them came from the fact of picking up the proper syringe for the tests going on and asking for "Bailey" and somebody else walks up and says, "Who do you say?" And he says, and he gives the shot to the wrong individual answering the call. That accounts for 99 percent of the diagnostic misadministrations over a number of years.

We have had a problem about how this written program was really the solution to stop those.

FACILITATOR CAMERON: So, in other words, look at the problem that actually exists out there and design your solution to fit that problem. I think we're going to go to the audience at this point.

(Laughter.)

FACILITATOR CAMERON: Carol?

DR. MARCUS: Okay. I think it's very important to decide what you want to solve before you decide what the regulation ought to look like. Having been a part of this regulation from the start because I was on the ACMUI for two terms during this, as I recall, what we really wanted to make sure of was that the wishes of the physician were appropriately carried forward to the patient.

The thing to understand is that the entire medical community opposed this rule. So did the ACMUI unanimously at the beginning. So did the ACMUI unanimously three years later. So did the OMB. Okay? So there was some disagreement as to whether what the NRC wanted to accomplish, in fact, would be accomplished by it.

The most telling thing is that last spring the NRC published a document about that thick which was a review of the QMP. And what it said was that it accomplished absolutely nothing at all, that the misadministration rate had not changed, that the principles were still very good, but it had no effect on the problem.

So I think we should not decide which part of it to keep but look beyond that back at the problem and say, "How do you get at that problem? All the things we did didn't work, cost a lot of money, infuriated the medical community, imposed bizarre requirements on medical practice," which is exactly what we're telling the NRC not to do, "and didn't get anywhere."

All through this process, I would explain to the NRC that California had come up with a different way to minimize the important mistakes, the therapeutic ones, by simply saying that the authorized user physician had to be physically present when the dose was given. And physically present meant in the same room.

There's no requirement for anything written for a program, for a prescription, for anything. And the very act of putting the physician there in nuclear medicine meant that like in the last, what, three, four years, we haven't had a single therapeutic misadministration. And the definition of misadministration in California is even more restrictive than that of NRC. It's ten percent.

So that is a way of decreasing problems. One of the things the ACMUI said many times when this rule was being discussed is: Look at where these problems are coming from. They're coming from practices where

physicians are not managing their practices, technologists are, and that most of these misadministrations were not caused by Board-certified nuclear medicine physicians.

There will always be a certain number of human errors that no one can ever fix but that if you have good qualifications for the people you authorize in the first place, you're going to get rid of a lot of these dumb mistakes caused by lack of physician oversight.

I just saw for the third time there's a hospital in New Jersey that has had a therapeutic misadministration in nuclear medicine. I reviewed them twice when I was a consultant on the ACMUI. They're still doing the same thing wrong. And it's still the same group of people that are not Board-certified in nuclear medicine that don't pay attention. So maybe you ought to look at the solution to this problem as a training and experience program, rather than as a written QMP program.

And the last thing is to make you realize that there will always be some low number of mistakes. With managed care and a decrease of the workforce, you're having fewer people do more work. And one thing that has been shown time and time again when you're looking at human error is that busy people make mistakes. Busy people take shortcuts and make mistakes.

One of the things you can do as regulators is to look at all the busywork you give us and figure out what you can take away to give us more time to pay attention to the important things, which is making sure the right patient gets the right dose.

Thank you.

FACILITATOR CAMERON: Thank you, Carol. There are a lot of common sense points there.

I guess I would be curious to go back to the agreement states and get some comments on the ideas that Carol proposed to test the idea about: Should we do Option 5 or should we have Option 2, for example? Aubrey?

MR. GODWIN: I think it makes a lot of sense if you're really concerned about exposure to patients where there's going to be a potentially significant outcome to look at the therapy area and to have the physician there.

I don't have a way to argue that California's outcome is not correct. And I think that this point should be brought to the Commission very clearly that this is one way to accomplish the significant part of it. If you want to go risk-based when you've got 100 millirem of exposure, there's a lot less risk than when you've got 100 rem.

So it seems to me that there's a lot of merit to looking at this option of going only with the therapy area and looking at who is present when the therapy doses are given. There will probably be some remote areas where this can cause a little bit of difficulty, they will have to be a little more careful in scheduling.

I could think of a lot of areas of the country where the physician is not there, but he ought to be in that immediate area anyway giving these things. So it seems to me like a good option.

FACILITATOR CAMERON: It's interesting to think about. Instead of having this label "quality management program" over the top, if you have the objective of make sure or decrease misadministrations, one option there could be to have a quality management program.

The second option could be to require the physician to be present when the whatever was administered. I mean, it's another way of looking at it, but it just underscores what's the purpose of the quality management program? And are there other ways to achieve that?

Bob?

MR. QUILLEN: Just for the record, I voted for Option 5 before it was ever put up there because Colorado

has not required a quality management program for its licensees. We are one of the renegade states.

I have to agree with what Carol said here. You have to identify what the problem is. And I think Jim did identify what the program is in the diagnostic arena. Our experience is very similar in how you solve that problem.

I don't think any written program is going to solve the problem of a technologist who grabs the wrong syringe because they're in a hurry.

FACILITATOR CAMERON: Does that reflect a consensus around there? I don't know. I don't want to put too fine a point on consensus, but do most of the agreement states around the table believe the same way, believe the way that Bob and the gentleman from Arkansas and others? Sure. Let's do a show of hands.

Let me ask the -- we don't know what question. This is great. We don't even know what the question is. All right. Who wants to contribute ten dollars?

(Laughter.)

FACILITATOR CAMERON: No. Let me just ask this: Do the states feel that there might be a more effective and efficient way to address the problem that the quality management program was ostensibly designed to address? I mean, is that a fair question? How many

states feel that there is a better way? Let's just do that show of hands.

(Whereupon, there was a show of hands.)

MR. PADGETT: Clarification.

FACILITATOR CAMERON: Yes?

MR. PADGETT: Aaron Padgett, North Carolina.

When you say there is a better way, why don't we just make that a little softer and say may be a better way because we don't have hard numbers, other things like this? Some of those things sound to me like they would be a better way, but again, nothing has --

FACILITATOR CAMERON: That's a good point. I don't want to -- this is not something that we're writing in stone here. Again a show of hands of how many out there feel that there may be a better way.

(Whereupon, there was a show of hands.)

FACILITATOR CAMERON: With that caveat that we put in there, was there anybody who did not raise their hand on that last one? And if there is, is it because they don't really care or they disagree?

(Whereupon, there was a show of hands.)

FACILITATOR CAMERON: Okay. Well, I think that's an important point.

MR. WHATLEY: I didn't raise my hand, but I'm not sure I disagree.

FACILITATOR CAMERON: Okay.

MR. WHATLEY: Kirk Whatley.

I put two little moustaches around my word "quality" management. Some of you all can figure out what that means. Several years ago when this whole issue came up, one of the things Jim failed to mention was that we retain the old NRC requirements in our rules that a physician -- the definition of authorized use was originally required by NRC, meaning that a nuclear physician would select the patient, prescribe the doses, and interpret the results. NRC got away from that for diagnostic.

And it's my understanding for most diagnostics, certainly, the things that don't require a written directive, that any physician can select the patient to receive radioactive material, that a physician does not have to be present, review anything about the condition before the patient is administered radioactive material. And then any physician, qualified or not, can interpret the results of that study.

I think that in itself, have a non-qualified physician being allowed to select patients, prescribe doses, interpret results, and everything, contributes significantly, more than anything else in my opinion, to diagnostic misadministration that we have.

I like the idea certainly of the therapist in California, but I never understood the quality management rule. Our rules in our opinion were more effective at dealing with this before the quality management rule ever came out. And we were basically forced to change it. And it could be compatible with NRC.

FACILITATOR CAMERON: Kirk, can you tie it a little bit? I mean, this goes into the whole idea of there are other ways to ensure quality. Can you talk a little bit about what your rules were like before --

MR. WHATLEY: The NRC rules would change several years ago when a group of people came into the NRC's medical licensing program from the community in my opinion did it the way they did it, as opposed to the way NRC had always required it be done.

NRC had always required in a license guide, and it was taught in that training program for all the rest of the licenses and inspections that a nuclear physician had three requirements: one, select the patient; two, prescribe a dose; and, three, interpret the results. That is not that way anymore with the NRC and hasn't been that way for many years. We retain that.

FACILITATOR CAMERON: To return to that old regime would be --

MR. WHATLEY: We're going to talk about training later, but for you nuclear physicians out there, if I was a diagnostic nuclear physician and I was practicing therapy or using I-131, I would be very, very upset if you told me I had to go take a course of 500 hours or 6 months somewhere to be qualified to do that, particularly when any physician is authorized to do that. Any physician can do that without going and taking any training.

But to be put on a license that says you're an authorized user and we don't know what authorized user means, in my opinion, I think we're doing a terrible injustice to require these physicians to go out and take that 500 hours of training, although I'm very much for it.

FACILITATOR CAMERON: Well, thank you, Kirk. I think that just underscores the point that people have been making from a different perspective. Let's go to Aubrey and then Dr. Carretta.

MR. GODWIN: I'm sort of from the old school, too. And I just never understood how the NRC could give the interpretation out that other physicians can do it when the only physicians that the agency knew the qualifications were the ones that were listed on that license. Anybody else may or may not be qualified. Yet, they are allowing these people to do work.

It really was a problem to me because the only person you know what the qualifications are is the one that submitted the application to you, the agency. And I find it very loose not requiring only those people to be involved in the selection of patients, prescribing the dose, and interpreting the results.

FACILITATOR CAMERON: Dr. Carretta?

DR. CARRETTA: I'd like to echo the two previous comments. I think as practicing nuclear physicians, we do exactly that. We review the requests. We determine the appropriateness of the study. We determine the dose. And we are physically present to review the history, examine the patients if necessary, and provide a consultative report.

We basically are not a laboratory type of practice, but we are a consultative type practice, where we work hand in hand with the referring physicians to solve the clinical problems. Unfortunately, what you've described has become more common in groups or practices that do not have Board-certified or special competency in nuclear radiology physicians, and it becomes a part-time versus full-time position.

Now, the NRC may not have to solve this problem. This problem is going to be solved by a greater agency known as HCFA because HCFA, which pays for all of

the procedures that we do for Medicare, is coming out with a notice of proposed rulemaking in November that will define three levels of physician supervision for imaging modalities. And the three levels would be: general, which means you have to be somewhere in the immediate vicinity, which can be the same city or state; direct, which means you have to be somewhere in the facility; and, personal, which means you have to be in the room where the procedure is being performed.

Diagnostic nuclear medicine will fall primarily under the direct and personal supervision with very little under the general supervision. Now, this has raised a fair amount of hackles in some of the medical community because it affects their livelihood and their ability to do diagnostic procedures.

But I think this solution, an economic solution, if you will, will have much more impact on the practice of diagnostic nuclear medicine than any regulatory solution that you might come up with with the quality management program.

FACILITATOR CAMERON: Thank you very much, Dr. Carretta.

Aaron, did you have a final comment or --

MR. PADGETT: I just had a follow-up. I missed the three. One was general, and the third one was personal. The other one was what, direct?

FACILITATOR CAMERON: Direct.

DR. CARRETTA: Direct.

MR. PADGETT: And what was the range area for direct?

DR. CARRETTA: Direct as currently defined in the federal regs is in the department or facility that's performing the study.

MR. PADGETT: Thank you.

FACILITATOR CAMERON: Okay. Good. I think we've had a good morning's discussion, and we're going to break for lunch. We're going to come back at 1:00 o'clock and get into training and experience. We have Lynn Roy with us, who is going to talk about the technologists' view on this, and also we have Dr. Cohen.

(Whereupon, a luncheon recess was taken.)

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

(1:00 p.m.)

FACILITATOR CAMERON: We're going to continue our walk through the cross-cutting issues. Cathy, are you turning this one over to Don or are you going to do it? Okay.

The next area that we're going to cover -- and, again, we don't have a whole lot of time, but we're going to do training and experience. And we have a couple of other areas. So we'll try to move quickly through so that we can end pretty close to schedule.

Go ahead, Cathy.

MS. HANEY: First we're discuss the training for the authorized user. And then the next step is we'll discuss the training for the radiation safety officer. We have considered training for the medical physicists and ancillary personnel, but I think, given time constraints, we won't go into those today, but we are open to taking comments in those areas.

As far as the authorized user goes, Option 1 was status quo. Under status quo, the rule has certain specialty boards listed. And you need to be a physician or they give you the option of a certain number of hours plus experience. So if you're not Board-certified, you can become an authorized user under the Board condition.

The first Number 2 is where the working group kicked in with some of our ideas of what we could do. Again, you need to be a physician first, plus a Board certification.

Under this item, we were not thinking about putting the actual Board names into the rule. We would have language that would say something like "certified by a Board whose process, certification process, includes the T&E requirements in Section B." And in B, it's the certain number of hours of training specified plus experience.

The thought here is that the type of training, the hours, and the experience would focus on radiation safety. And there would be less emphasis on the clinical component. We'd be focusing on receiving and order radioactive materials, doing dose calibrator calibrations, spill control procedures, and cleanups, plus a certain number of patient cases. But, again, the emphasis on the hours of training and the experience would strictly be radiation safety.

Alternative 3 is the same as 2 except we've added an exam. The exam would be used to verify competence in the area. The exam would focus on radiation safety issues again.

The question has been raised as to who would give the exam. We have not gotten any further down into detail other than saying NRC could give the exam or NRC could approve an organization that was going to give the exam or NRC could say, "This is what we think should be on the test and in the process. And as long as you incorporate those items, then you're fine." So, again, we're still at a very high tier and level on some of these items.

For Number 4, it says that if you are a physician, you can use radioactive materials. The working group did not feel comfortable with allowing this alternative for all of the modalities, only for the low-dose modalities. So this item was somewhat limited.

Number 5 is the physician plus the exam. And that would be it.

And Number 6 is physician plus an exam plus clinical experience. And the clinical experience would only focus on patient cases. There would not be a radiation safety experience component in this. And the figuring here is that we would pick up whether the particular authorized user knew it under the exam requirement.

That's a quick overview of this area. So, Chip, it's yours now.

FACILITATOR CAMERON: Okay. Thanks, Cathy.

Again, if there are other alternatives, let's get those out on the table. These are all very specific options. Does someone have a context statement for this whole area? There have been a whole lot of references to training and experience this morning. Maybe I'm looking --

MS. HANEY: Actually, there might be one more thing.

FACILITATOR CAMERON: -- for something that isn't there.

Yes, Cathy?

MS. HANEY: Yes. Let me just say one more thing. When we're looking at the number of hours and the type of exam, it would be modality-specific. So as you got up into the higher-risk activities, more training, more number of hours would be required. And I think that's important to bring out.

We did do some tests, rule texts that accompanied the papers that went up on the internet. And that was only for the 35.300 modality. So if you do go to the home page and start looking at that, realize that that was only for that modality and the number of hours would change for the other modalities.

FACILITATOR CAMERON: Okay. Aubrey, do you want to lead off?

MR. GODWIN: Thank you.

I guess before I can get really fixed on this, I need to know what you want to require as an authorized user because it makes a difference whether this person is the one who's going to be the responsible party for just handling the ordering and receipt of radioactive material or is this person also going to be responsible for selecting the patient, describing the dose, and interpreting the results?

Now, I'm going to take two positions here and let you try to figure out where I'm going.

(Laughter.)

MR. GODWIN: Let me know if you figure it out.

If the authorized user is to select the patient, prescribe the dose, and interpret the results, particularly for any procedure that has an organ dose of other two rems, whatever number you wanted to use, I feel pretty strongly we ought to look at two, preferably three, but two or three, where they're Board-certified or have a specific number of hours.

I would like to see an exam in it. But I would prefer to reserve my judgment a little bit on the exam until I find out who's giving it and how it's given.

For those lower-dose procedures, if you would, many of the diagnostics, and where the individual is not doing the administrative work of maintaining the radiation safety program, I might look at some of the four, five, and six operations.

But I feel very clearly that any individual that is on a license needs to be specially trained relative to the radiation safety. And I like Board certification because that probably means that he also has the clinical experience.

I'm not sure how you're going to address the clinical experience. I feel strongly it needs to be addressed in 2 and 3 somewhere, and it's not shown in there anywhere as far as the number of hours.

So I really can't select one until you sort of define what you're going to have as an authorized user. If you do not restrict the use to the authorized user, then I think we have some problems to discuss.

FACILITATOR CAMERON: Don?

DR. COOL: I think perhaps we need to try and flesh out both versions because I don't think a choice has been made yet. Part of what we're trying to hear is exactly how that should play in with the issue that came up this morning on what an authorized user does or doesn't do, which is not one of the ones that was up there.

While we're going through this discussion, a little bit of a context in here and perhaps a little bit of a radical thought for people to shoot down if they choose.

One of the things that has been tossed about, quite frankly, is what purpose does NRC serve in regulations by specifying anything with regard to the physician's knowledge of the medical activity in terms of prescription, leaving the scan for those sorts of activities.

So one of the things that I would like to have comment on as you're looking at this and, in fact, one of the things that underlay some of these, is that the hours of training and experience might well focus strictly on the safe handling and use of the material, not on whether or not the individual can or cannot read the particular scan. Leave that to the medical boards to practice, the various societies, other credentialings to HCFA, whether or not they want to reimburse them for reading those scans and otherwise.

So I would like some comment because what's embedded here and probably isn't clearly 1, 2, 3, 4, 5 is what hours you're referring to and what's the experience you're referring to and whether or not those should be strictly limited to more like what we do for any other

kinds of things, radiographers, others. Do you know how to use materials? Do you know what dose is? Do you know how to handle those materials? Do you know how to deal with loose material if you're dealing with unsealed sorts of activities and say you know?

So that's a context for you to describe, and that's separate from the issue which Aubrey is bringing up, which is a specification of authorized users, as I think we're hearing. California shall be present and be more specifically involved and present during the administration.

FACILITATOR CAMERON: Before you talk, Aubrey, Don, in relationship to what you just suggested, where does that fit in relationship to these options? Number 4?

DR. COOL: Two, 3, or 6. Anyplace that you see except in status quo, consideration of number of hours of training and experience, a subset of that could be whether that is similar to or we do now, which gets into a variety of things which could be contended, have nothing to do with the safe handling of material.

FACILITATOR CAMERON: Okay. Thank you.

DR. COOL: So you could read it any one of -- actually, I would have to look at it as a subset in looking at the particulars, which version of it is and how far do you go in terms of certification. I think already

this morning I have heard countervailing views of those two subjects on each side.

FACILITATOR CAMERON: Okay. Thank you.

Stuart?

MR. LEVIN: Levin from Pennsylvania.

Just a quick question to the NRC. Was it an oversight that you didn't include D.O.'s with the M.D.'s or you just mean physicians generically when you made the slide?

DR. COOL: The slide was intended to be just a generic reference. This was not at this point any intention to kick out any particular subspecialties or otherwise but for a shorthand version.

And if people have a better lingo on how to capture that without starting to write long paragraphs and including all of the various doctors of and otherwise, then help me out. Our intention was simply to say physician.

FACILITATOR CAMERON: The word "physician" will take care of it is what we heard from the audience. For your purposes, D.O. is a doctor of osteopathic?

Steve Collins?

MR. COLLINS: Steve Collins, Illinois.

Part of my statement I guess goes to your question. And that is I'm not sure we can answer the

question of what training and experience we want until we define what it is these people are going to do. And that goes back to what Kirk Whatley was saying and Aubrey was then saying.

If we're going to require a trained physician to directly supervise the use, even the HCFA direct or to actually be physically present in the room, we'll come up with a whole different list of qualifications than we will if we're going to allow what some of us have got ourselves into that we don't like with circuit-riding physicians and stuff where he's not there to see the patient.

The test follows a procedures manual and administers whatever the attending requests the study for. The request usually says "Name of Patient" and "Lung" or "Bone" or whatever. It doesn't say which bone agent to use. And the nuclear medicine physician is not there to say which one is best for the type of study really needed. And there's no conference between the nuclear medicine physician and the attending to determine that usually. Then when it comes time to read the films, frequently the tech has already gone home at the end of the day and there's not much communication there either.

So the answer to what we're going to get to on training and experience is going to depend on how that relationship is expected to be. So I think that needs to

be maybe defined better before we can answer this unless we're going to try to answer it for every permutation that we have.

FACILITATOR CAMERON: So that's sort of that threshold issue.

Cathy?

MS. HANEY: Yes. I can tell you from the standpoint of the working group, we were looking at the authorized user as being responsible for the safe use of the material. We did not take it to the level of reading the scans.

This is a particular area where the medical policy statement becomes very important and how that policy statement is written because if you go to some of the options that we have for the policy statement, we could not put in a rule that would take us as far as who can read the scans and what training do you need to read the scans.

So, at least from the standpoint of the few meetings the working group had, we limited it to safe use of material.

FACILITATOR CAMERON: Okay. So at the least --

MS. HANEY: Yes. That was where we were. But, at the same time, I have no problem with expanding

that. And with your training needs and the approach that you would want to follow, would it be different?

One of the things that would really help us in this area is: Is the exam needed? Is the exam the right way to go or not? Do you feel an exam is needed to verify competence? And does that again need to focus more on radiation safety than what currently some of the certification exams are? So that's a key item to us.

FACILITATOR CAMERON: Okay. Thank you for that clarification.

Steve, do you want to address the exam question before we go on?

MR. COLLINS: I just want to follow up on what you were saying. In that context, then it comes down to where is the authorized user going to be? If the authorized user is going to be in the facility, then the amount of supervision and specification and training and qualification of all of the other workers is less.

If the physician is not going to be required to be at the facility and is usually not going to be there when the radioactive materials are actually being used, then we really need to be looking at training and qualifications of somebody else, the one that's actually using, handling, administering, drawing up doses, making

sure they're accurately measured. That's where we need to be looking for radiation safety purposes.

FACILITATOR CAMERON: Can we assume that -- I mean, that's the focus at this point?

MS. HANEY: Well, there is a focus, but at the same time I guess maybe we should step back and ask the question of: Where would you like to see us go? I can tell you I've told you where the working group went, but that's one path. And we're not too far down it that we can't back up and say maybe we took the wrong path and we should be going down the other one.

So maybe the first question, Chip, is: Would you prefer us doing T&E toward the choice of the patient, the administration, and the reading of the scan, or toward the approach that we took, which was just the radiation safety?

And then based on which way the group thinks that we should go, then we can revisit how we get there.

MR. COLLINS: When I answer that question, I always put myself in the position of I'm the patient and I want that nuclear medicine physician holding my hand, talking to me, and telling me all about it, explaining it, and making sure it's the right study done the right way the whole time.

And most of the nuclear medicine docs will probably, "You're an unrealistic patient. I'm glad you're not mine."

(Laughter.)

FACILITATOR CAMERON: I'm not going to touch that one.

Ruth?

MS. McBURNEY: Well, getting to what Cathy was saying and what I mentioned earlier, if we look at it from the context of the medical policy and if we're truly getting out away from the practice of medicine, then that's hand-holding explanation I guess would be practice of medicine.

And then the training and experience would be more toward the radiation safety and the handling of materials, regardless for anybody that is doing that, whether it's the authorized user. And then, of course, in therapy that would be the case hopefully.

And if we're going to be focusing more on radiation safety and so forth, then I think if we went with Option 2 or 3 that we would need to look at the Board certification and whether they put any emphasis at all on radiation safety in those exams that they give because, as I understand, there's not on that. It is more on the clinical end of it.

FACILITATOR CAMERON: Okay. Thank you.

Stan Marshall has had his card up for a while.

MR. MARSHALL: I had what I thought was a simple question, and it's broadened a little bit. I think my question has actually changed based on the qualifications.

I want to give just a comment as an example. I think you had an early question about: Is there any example up there? I think my answer was yes.

Based on a letter I have on my desk in the office from a physician, he has patient selection, prescription, administration, and evaluation, doing all those things under authorized user.

He feels that his medical license and certification by a particular board, by one board, not all boards, as mentioned under Number 2, should be the only option, no alternative training short of a board certification in a specific discipline. That's a rather extreme specific case, might be described as very self-serving.

When we qualify what a authorized user might be or might not be, I guess I'd go to the example we have in this country about mammography certification, where we have drawn the line in the sand between "the technologist who handles the machine, positions the patient, and

administers the radiation," unquote, versus the physician within practice of medicine that selects the patient and evaluates. And we seem caught short of doing that at this time.

FACILITATOR CAMERON: Okay. Thanks, Stan. I think we're going to probably get some clarification when we go out to the medical community on some of this.

Ed?

MR. BAILEY: Bailey from California.

I think our common experience sort of gets us muddled because we know situations where the physician will have a variety of roles. I was looking at this and saying, "Well, if the physician is also the radiation safety officer, maybe they need some training that the physician who has a staff of 20 health physicists and medical physicists there to help them doesn't necessarily have to have."

But then it's almost an impossibility because it tends to be the smallest facilities that you would then have to have the more qualified doctor at. And that's probably not going to be the common rule.

So that we're going to end up -- and if I'm wrong, you all yell at me, but quite often the smaller the facility, we end up with the M.D. being the radiation safety officer or one of the technologists being the

radiation safety officer. And we sort of need to separate those two job functions.

If we're talking about the physician just practicing medicine, then I think certainly they've got to be a doctor and the Board certification or some very stringent equivalency has to be -- I mean, I could not in good conscience get an application in from a doctor who had no background in nuclear medicine and wanted to get a license.

Now, I'm hearing NRC say what I don't think I like. And that is they can't dabble into the practice of medicine enough to say that an authorized user has to do the interpretation or an authorized user has to prescribe. If that's the case, then any hospital can get a license by putting down any M.D. on the license if -- I mean, that's the ultimate to that situation.

So I think we've got to separate the two. I think the doctor has to be very qualified, has had training. And we do have a thing here in California that's a little different, just one thing. In the X-ray program, we do require every physician who is not Board-certified in radiology to take what amounts to a radiation safety exam.

Now, I will not defend it as being a definitive and difficult exam to pass, but I will say that

it's going to be difficult in my opinion to make an exam too difficult for doctors to pass because in their career of 20 years of going to school, they've taken 13 or 14 tests. If they're good at anything, they're good at taking tests. And for the most part, they can learn things fairly rapidly.

This may be an option to look at, a safety syllabus, which didn't have an exam based on it.

FACILITATOR CAMERON: Don and Cathy, did you catch that one?

MS. HANEY: Yes. Actually, if I can make two comments, one being I was just bringing up the fact that we're somewhat limited by the medical policy statement as far as how we can go, but now is our chance to change the medical policy statement. So if you see us going down that route, then maybe we need to make sure that the policy statement that we put forward would allow us to do that.

The other comment that I had is on the radiation safety officer in differentiating them from the authorized user. The working group did do that, and we'll get there in a minute. But let me suffice it to say that under status quo, if you are an authorized user, you can automatically be a radiation safety officer.

In Options 2 through 5, that's not a guarantee any more. They're treated as individual people. And it's very possible that an authorized user may have to go on and take some more training before he could be classified as the radiation safety officer. So I think we did address that point.

FACILITATOR CAMERON: Don Flater while Don is stepping up to the mike.

MR. FLATER: I've got three points to bring up, one that I haven't seen mentioned here anyplace. And it's one in the states we at least have to deal with. And that's grandparenting. When are you going to slam the door? What are you going to do with those folks that are out there before you slam the door? I think that that's something that certainly has to be considered in anything that you do.

The second thing is I would caution you on the word "physician" because in some state laws, physicians can be more than D.O.'s and M.D.'s. They can be things like chiropractors. They can be things like podiatrists and those kinds of things in some state law. So don't assume that the word "physician" means only the people that practice medicine. They may not be.

The other thing is on the exam. And I heard Cathy I think when she brought it up that NRC would give the exam. Does that mean exclusively NRC or not?

MS. HANEY: No.

FACILITATOR CAMERON: Okay. Clarify that for the transcript.

MS. HANEY: Just one of the options that we thought about was that NRC could give the exam, but we were also thinking just as much as we could give the exam that we could approve or review another organization's exam or we would set up criteria. And if your exam meets this criteria, then you're fine. So it would not be the only way you can become qualified is to take NRC's exam.

MR. FLATER: I guess part of the qualification I was wanting on that was if that was something that was going to be put upon the agreement states and we were going to have to set up a group to deal with the exams.

I don't know. I'm not saying whether I want to do that or I don't.

MS. HANEY: Yes.

MR. FLATER: And that's where I was coming from.

MS. HANEY: Okay. Yes. We didn't get down that far into that. It was more a question of: Do we

need an exam to verify someone's competency? That was where we stopped on the exam question.

MR. FLATER: In looking at the exam issue, I would suggest that you seriously look into the validation of examination because if you want something to drive costs up, you want to look at something like that. And so the use of existing exams that are already valid are probably much more pleasing than coming up with our own exam.

FACILITATOR CAMERON: Let's go to Kirk and over to Aubrey, and then we have a couple of statements from the public to put on the record.

MR. WHATLEY: Kirk Whatley, Alabama.

I'm not aware of any physician who actually aleuts generators on a daily basis or a weekly basis or a monthly basis. I'm not aware of one that prepares doses. And I'm not aware of one maybe with the exception of some therapy doses who administers doses to the patients. I don't know of any that do surveys on a routine basis or handle waste disposal or anything like that. I'm just not aware of them. Perhaps you are.

It's usually not the physician who picks up the wrong syringe or vial and draws the wrong material from it and gives it to the wrong patient. It's usually not the physician who calls the wrong patient in to

receive a dose. Usually it's the tech. And we don't even look at the training requirements for these folks.

I'm not sure we're looking at the radiation safety requirements for the right people if physicians normally don't do this. And it's my belief that most of the radiopharmaceuticals in our state come from radiopharmacies. We have very little doses that are actually prepared in hospitals or even private offices now. Basically it all comes from, as I said, radiopharmacies.

If we're really looking at radiation safety, the people that are handling and preparing and using radiation material on a daily basis, we don't even talk about the people that do this.

I think it's an analogy linked to perhaps training a radiation safety officer in industrial radiography and then letting the people who don't even look at the qualifications of the people who want to go on and use the source on a daily basis.

I've always questioned the real need for requiring physicians to go through some of the training that we require in radiation safety. I've often asked myself: What are we really doing that for?

Those are just some comments.

FACILITATOR CAMERON: Thanks, Kirk.

Let's have one more comment from the table. And we'll get back to those people at the table, too. Aubrey, do you have something to add here?

MR. GODWIN: Yes, if we're going to have the exam and the decision made not to look at the text, which I think this would be hard to look at also, I see the exam being basically a radiation safety exam.

Don asked the question relative to clinical. I think it is important that the physician who is going to be doing high-dose procedures has some clinical experience. I think this will reduce the exposure to patients, which is one of the things we've got to look at as a radiation safety function to avoid, to some degree at least, the unnecessary exposure in lack of knowledge.

I don't know if you can say that someone is properly prescribing. So you would have to look at this if it would help in assuring to the patients and to the public in general that the physician involved has at least a chance of being knowledgeable in the selection of patients, prescribing the dose, and interpreting the results. And I think that's a very important thing in the way of radiation safety.

Now, beyond that I'm not sure you need to go, but I do think that clinical experience is an important thing that should be in some way brought into this. And

if it calls for rewriting the mission statement, then do it, but we need to look at that.

Radiation safety, I agree with Kirk that we need to look more at the people who are doing some of the work itself and ensure that they're properly trained. And I'm not sure the guides clearly enough address that at the present time.

FACILITATOR CAMERON: Okay. I think that the statements that we're going to get from the medical community may help to tie some of this stuff together. First I'd ask Dr. Cohen, who is President of the California Chapter of the American College of Nuclear Physicians, to come up. And then I believe we're going to hear from Lynn Roy on the medical technologists' issue.

DR. COHEN: We'd like to talk about training and experience in the context of the quality of medical care. Changes do not take place in a vacuum. And the process of revising Part 35 is not exempt from this dictum.

The process takes place against the ever-enlarging background of managed care. Managed care some would call managed costs. But the other side of the coin is the quality of care.

As Dr. White has so aptly pointed out, it's difficult, if not impossible, to maintain the quality of

care with ever-increasing costs and ever-decreasing reimbursements.

We must never lose sight of the fact that the patient comes first. The NRC has historically recognized this fact. I'm old enough to recall some of the old NRC regulatory guides where the very last statement stated that "Nothing in these regulations shall be interpreted as interfering with the care of the patient." And I'm glad to see your thoughts are leaning back in that direction because this principle continues to be of increased importance today in this era of managed care.

The quality of care in nuclear medicine includes both radiation safety and the clinical competency of the physicians in this line of practice. Part 35 deals with the issue of radiation safety but has two current flaws which have led to major controversies.

First, it contains provisions that have been interpreted as interfering with the practice of medicine and pharmacy. And, second, it only deals with byproduct materials and ignores other sources of ionizing radiation.

On the other hand, radiation safety programs operated by individual states tend to regulate all forms of ionizing radiation based on standards set by various organizations of recognized expertise.

The NRC could certainly benefit the delivery of health care and protection of the public by establishing flexible standards of radiation safety which could be incorporated into state programs with recognition of individual community standards.

The knowledge based needed to implement an adequate radiation safety program for byproduct materials is relatively independent of the organs to be studied or the nuclides to be used.

Some states may still have difficulty developing the expertise to run a program where they may not have this desire. And this should be recognized in any revised Part 35 so that such states can be encouraged to contract with other states or form compacts to accomplish this important aspect of quality of care.

The NRC regulations, which have led to claims of interference with the practice of medicine and pharmacy, are an indication of the NRC's sincere concern with other aspects of the quality of patient care. But these concerns are misplaced.

Some of these concerns are already adequately addressed by state laws covering the practice of medicine and pharmacy. The other aspects of the quality of patient care are adequately addressed by many other entities.

Certification of competence to practice nuclear medicine is regulated by various specialty boards, which are then accredited to perform this function by the Accreditation Council for Graduate Medical Education, ACGME, who also approves the standards and content of such training.

This process is further implemented at the local hospital level through their bylaws, which contain a single standard for the credentialing and delineation of privileges of practitioners in all specialists.

This process is carefully monitored by the Joint Commission on Accreditation of Health Care Organizations, JCAHO. A conjoint statement on credentialing and delineating of privileges was published by the Society of Nuclear Medicine and the American College of Nuclear Physicians in the January 1991 issue of the Journal of Nuclear Medicine and the very last statement in this document, quote, "reiterates that Nuclear Regulatory Commission licensure or equivalent state licensure is a reflection of training in radiation safety procedures only and does not imply clinical competence in the areas stated above."

Unfortunately, this fact is poorly understood at the local hospital staff level, where they tend to privilege physicians for every license procedure, whether

or not they have demonstrated current competence to perform all of these procedures.

There's been an evolution in the concepts of privileging and credentialing. And the current standards can be found in JCAHO's comprehensive accreditation manual for hospitals.

These current standards require that deliberations regarding the initial and the reprivileging, usually every two to three years, of physicians should include quality assurance data, such as reviewing charts for appropriateness, prescription of the dose, interpretation, and so forth, as well as continuing medical education, CME, courses or training plus a statement of demonstrated current clinical competency to perform the requested procedures.

Unfortunately, there are still problems. CME training is supposed to be obtained in your area of specialty. While, obviously, of course, interstate planning would not apply to any specialty, the problem is that many hospitals and states have permitted many specialties to stretch the definitions.

For example, an endocrinologist may obtain all his CME credits in diabetes, pituitary, and adrenal diseases with no courses pertaining to his use of bone

densitometry even if his practice entails a great deal of this procedure.

Another example, a radiologist may have all his CME credits in CT, MRI, and ultrasound, even though he spends 20 percent of his time doing nuclear medicine. The fact is many physicians go for years without ever taking a CME course that pertains to their practice of nuclear medicine.

This standard should be tightened up by JCAHO and state licensing boards. It can be accomplished simply by requiring that the percentage of CME credits pertaining to nuclear medicine should be roughly equivalent to the percentage of professional hours spent in the practice of nuclear medicine.

The standards for demonstrated current clinical competency are also frequently stretched in nuclear medicine. While a surgical service would never permit a Board-certified surgeon to perform a whipple operation if he had not done one in the past ten years, there are other problems in other specialties. And the constantly increasing complexity of nuclear medicine procedures necessitates more realistic and appropriate standards.

If a physician is more than two or three years post-residency training in any specialty, he should not be

given automatic privileges to perform all possible procedures.

The radiation safety aspects of most diagnostic nuclear medicine procedures are similar, but the required clinical and technical skills may vary widely. Again, this factor tends to be ignored in many hospitals, whose privilege for all license procedures without any evidence of current competency.

Obviously this item also needs to be more closely monitored and enforced by both local hospitals and the JCAHO. This can be accomplished by using a simple reprivileging standard, such as, quote, "The types of the standard for reprivileging should be based on the number and types of procedures performed since the previous privileging and should be commensurate with the standards used by other hospital departments." In other words, what's good enough for the surgeon should be good enough for nuclear medicine.

Nuclear medicine tends to be a specialty that is poorly understood by those not in the field. It, therefore, will be necessary to up JCAHO's understanding of nuclear medicine as well as the understanding of hospital staffs and state boards of medical licensing.

These efforts plus the revision of Part 35 hold the key to maintaining the highest standards of

radiation safety and other aspects of quality patient care. This approach also has the distinct advantage of utilizing existing entities at little or no additional cost.

Thank you.

MR. WANGLER: My name is Ken Wangler. I'm from North Dakota.

JCAHO, maybe you could explain that a little bit because I know that not all hospitals are a member of that or participate in that.

DR. COHEN: If you want to be reimbursed by Medicare, Medicaid, and most insurance companies, you must be accredited by the Joint Commission on Accreditation of Health Care Organizations. They now also monitor outpatient facilities and have a separate manual on outpatient faculties, where it used to only be hospitals.

FACILITATOR CAMERON: I want to go back to you to get some questions or comments on Dr. Cohen's presentation, but I really would like to get Lynn Roy up here to give us her perspective on this. So then we'll have it all.

MR. FLATER: I just want to clarify the doctor's statement. I'm sorry to disagree with him, but, at least in the State of Iowa, probably two-thirds of our hospitals do not belong to JCAHO. They are accredited by

the State of Iowa, by the Medicare body within the state. So you do not have to be accredited by them.

FACILITATOR CAMERON: I think that Dr. Cohen did mention state licensing boards, but a good point.

Lynn?

MS. ROY: Nuclear medicine is just not about injecting and handling radioactive materials. That's not why it exists. It's about providing information to physicians to treat a patient with the desire to make them better.

You can have perfectly wonderful safe handling of radioactive substance. And if the study isn't performed appropriately and if it's not interpreted appropriately, you can have far more poor outcomes than if you injected a higher or lower dose. And I don't have to waste anybody's time in describing that. It's a process. And you cannot take apart each process. You can, but you're not accomplishing anything.

Nuclear medicine technologists, -- and I think the gentleman over here is correct -- we either prepare radiopharmaceuticals if we're not getting them from a radiopharmacy or we get them from a radiopharmacy, we calibrate them, and we inject them. We do this from an order from a physician.

After we do that, we have to image the patient. And there are all kinds of techniques and all kinds of positioning that you have to go through to get that. You develop the film, and then you give it to the physician to interpret.

There is a very strong correlation with the success of that whole process with the education and the training of a nuclear medicine technologist and the physician. The technologist section strongly supports certification and licensure, so much so that we've joined forced with the ASRT to try to get the Randolph bill, which was enacted in 1981, which required states to have technologists using ionizing radiation to have licensing, which requires education.

There are two credentialing boards currently in nuclear medicine: the ARRT and the NMTCB. To have to get one of these, to be accredited by them, you have to graduate from a school that is accredited. These schools offer many, many hours in radiation safety, proper handling of radiopharmaceuticals, and everything else that goes into nuclear medicine.

I don't believe and the technologist section does not believe that the NRC should be involved in setting those standards. I don't believe they have the experience in deciding how many hours of biochemistry,

physiology, and anatomy that a nuclear medicine technologist needs to take. They don't do that for physicians.

However, if the NRC is interested in assuring that only educated, well-trained technologists do perform these procedures, we would like to invite you to join with us in assuring that the Randolph bill or something very similar is enacted so we can assure that we have qualified, well-trained technologists working doing nuclear medicine procedures.

Thank you.

FACILITATOR CAMERON: Thank you very much, Lynn.

I'd like to hear some reactions around the table to what we've just heard and try to tie some of this together. David, you have been there for a while. Do you want to make a comment before we go back up here?

MR. WALTER: Yes. This is David Walter from Alabama.

A number of the states that are represented here today already have required technologist certification programs. Unfortunately, that's a minority at this point.

One of the things that the CRCPD group or part, key group, is going to talk about on Monday and

Tuesday of this week here in L.A. is a minimum training and experience qualification criteria for technologists to be added into the Part B suggested state regulations.

We've known that this has been a problem for a long time. We just had not really acted on it on a national scale. And a number of states took the initiative to go ahead and do this on their own.

We are drawing from those states and their experiences in this to try and put together as good a program as we can to be put into the rules. So we're going that direction. All right? That's the first thing.

The second thing, earlier today we heard about the presence of the physician, the authorized user, in the facility for whatever study is going to be done. And with the growth in teleradiology, it's just not going to happen.

I don't care what happens with HCFA right now. I know that it won't last. It's not going to be approved. I can't see it being approved that they turn down the payment of a diagnostic nuclear medicine study via teleradiology simply because the physician wasn't there.

So we need to be able to take that into consideration also when we go through our training and experience requirements for someone being on site if necessary.

FACILITATOR CAMERON: Thank you, David.

Does anybody want to pick up on Dr. Cohen or Lynn Roy, on their presentation?

MR. COLLINS: Steve Collins, Illinois.

Illinois is one of the states that does, in fact, have test accreditation requirements. We recognize both testing by the two organizations she mentioned as meeting our requirements. The only thing we have on that is CEU credits, a certain number of hours to maintain that. So we do believe that's necessary and have adopted that. And we think for those people who are the ones using the material, that's the right way to go.

In that context, that's the reason that we can say if the physician is not going to be there in the room when use of radioactive material is going on, then we're not sure you need the physician as an authorized user if the medical policy is changed to say, "We don't get involved in the practice of medicine."

If it's only going to be radiation safety, then we're not sure if the physician is not going to be there that they need to be tested or anything else. So one of your options that's not there is: Who cares in that particular case? But there's a whole set of ifs that go into that qualifying statement.

With regard to the practice of medicine, one of the problems we get into is the fact that most of us don't believe that the boards of medicine or the physician professional organizations have or are, in fact, going to be able to limit the practice in those fields of medicine to those people who are really qualified. If, in fact, they could describe how they are going to accomplish that, then we can back totally out of it and look only at the radiation safety aspect and simplify this whole thing.

FACILITATOR CAMERON: I think that clears a lot of the confusion up, at least for me.

I want to quickly go through the cards and the people in the audience because we do have to move on to the next area now. Let's start with Bailey and then Quillen right here and then go on down the line and go back to Arkansas and Carol Marcus.

MR. BAILEY: California is also one of those states that requires certification of the technologists. And I would agree with everything that's been said about the importance of the technologists being trained and receiving continuing education. I think it's been a great benefit.

I guess putting back on my regulator's hat a little bit, it also has enabled us in several situations in this state to basically fix blame where blame belonged,

where a patient was stuck with a needle that had already been used on an HIV patient, where the wrong patient was injected with labeled white blood cells. It wasn't anything that the doctor had to do with that. It was a technologist who wasn't being very conscientious about what they were looking at.

I still have some problem with in any way allowing the doctors to get out of any responsibility because in California, there are one of two entrepreneurial types. I can tell you that if you don't have the doctor very, very closely and legally tied to this operation, you're going to see what we have seen in some cases where a tech buys a machine and he goes out and he contracts with somebody to do something. And there are people whose primary concern is not the health and welfare of patients. And their primary concern appears to be making money.

I think it's a very important team. And both of them have to be recognized and held accountable for what they do.

FACILITATOR CAMERON: Okay. Thank you, Ed.

Bob?

MR. QUILLEN: Quillen, Colorado.

My comment's based upon roughly 12 years of working in a teaching hospital. From that experience, I

would say from a personal point of view, as far as the physician is concerned, I am most interested in their qualifications as a physician, not as a radiation safety expert.

One indication of that is: Do they have Board certification? So when I look at a physician, I look for the Board certification. This is a personal preference.

But the physician is not the person who is handling the radioactive material except in very rare cases. It's the technologist who is handling the radioactive material. And under the current scheme, we do not look at the technologist. We do not evaluate the technologist.

Colorado does have and has had certification requirements for mammography technologists before in the U.S.A. That's because we had one state legislator who was very interested in that topic, but we don't have that for nuclear medicine. And this is the missing link in this whole issue of training and experience.

FACILITATOR CAMERON: So some states, Illinois does have requirements, but most states do not. Okay.

Aaron?

MR. PADGETT: I'll see if I can muddy the water just a little more. Aaron Padgett, North Carolina.

We at one time had a rule that said the physician had to be in the facility where the patient was being treated. There was a bright, young female physician who said, "Up yours."

So being good bureaucrats, we said, "You'll do it our way or you won't do it."

Well, when the judge looked down from his podium and said, "Mr. Radiation Protection, where is your medical degree that allows you to tell her how to practice medicine?"; essentially, we lost the case. So there's probably a player here that we have not talked about yet, and that's the Bar Association and the local judges, as we found out.

MR. BAILEY: Can I just make one quick response to that?

FACILITATOR CAMERON: Yes.

MR. BAILEY: As much as I hate to admit it and I wish that weren't on the record now, there is some advantage to being in health departments because when they come out from a health department, in general you have somebody that is the state health officer and that judge loses his argument because I can guarantee you that when we take an action against a hospital or a doctor, there's going to be somebody in my department that is going to say, "Now, is this really necessary?" They'll usually

support you all the way up, but they'll look at it closely before they will agree that you're going to do something real drastic.

FACILITATOR CAMERON: Okay. Thank you. Thank you, Ed.

Ruth?

MS. McBURNEY: Just to speak to the technologist issue. And this also came up at the ACMUI meeting. We in Texas felt that it was so important -- we have not put it into our regulations yet, but we did form a consensus group that was made up of technologists, nuclear pharmacists, and radiation safety officers at medical facilities, and some of our regulatory staff to come up with what would be the minimum criteria for the technologists. We are putting that into our regulatory guide as acceptable training and experience for the technologists in licensing medical facilities.

Now, I've given that information to Cathy for the working group's consideration.

FACILITATOR CAMERON: Okay. Thank you, Ruth.

Don?

DR. COOL: Just a quick point. And it's something that seems to be going at least in the rural areas. And that is what is allowed for a physician's assistant to do? They are ordering nuclear med exams,

those kinds of things, already. And we're seeing them specialize in other areas.

So I don't know whether they're going to come into the radiology area or not, but at one time Kentucky had a school that they were training them to be physician's assistants in radiology. That may be another area because those people certainly are not M.D.'s.

FACILITATOR CAMERON: Okay. Thanks, Don.

I just wanted to get a clarification from Lynn Roy. You heard Illinois talk about their requirements. Is that something that the technologists support or don't support? I was just trying to get a feeling for how the industry -- could you just speak into the mike? I don't want to delay things here, but I was a little bit confused about that.

MS. ROY: The end result obviously is competency because you can take all the tests in the world and have all the CME credits in the world and not particularly be competent, but there's only so much anyone can do. So one would assume that if you had so many hours and so many topics and passed the test, that yes, you are competent.

We would like to have people take recognized national tests, such as the NMTCB and ARRT, but we would

also support -- and it would depend on how each state structured their own particular exam.

The State of California, where I happened to be in, they recognize the NMTCB. You also can take the state license test in nuclear medicine in California, but it's very, very similar to the NMTCB. So we would support that.

What we do want is to have certified, trained individuals because that is going to assure better outcomes. And how that is accomplished, it's probably not as important as: Is it accomplished?

Sometimes the means overwhelm the end. And I think we need to look at the whole process and outcomes and: What do we really want to gain here?

FACILITATOR CAMERON: Okay. Thank you. Thank you very much.

Jared and Carol, I'm going to have to ask you to be real quick because we've got to move. Jared?

MR. THOMPSON: Jared Thompson in Arkansas.

As a license reviewer, this is one of the things that gives me the most heartburn: reviewing physicians' credentials. I detest calling a physician and telling him that he's not qualified. It makes my upper management real nervous. They squirm.

And I can't see offering an exam and saying, "Hey, doc, by the way, you also failed your radiation safety exam."

(Laughter.)

MR. THOMPSON: Things need to be simplified as simply as possible to keep us as licensing people out of that situation of trying to tell docs whether they're qualified or not.

FACILITATOR CAMERON: Okay. Thanks. That's sort of a good thing to have on the record at the end.

Carol?

DR. MARCUS: A couple of things. First of all, please understand that under eery state's malpractice law, the physician is ultimately responsible for the quality of the medical practice that takes place under his responsibility. While you may look at whether it's the tech or the doc, in court it's the doc.

Number two, physicians handle radioactive material and inject patients all the time. You may not see it. I inject patients all of the time. Please understand that physicians have to know how to handle radioactive material.

Some places the physicians will milk a generator or make up a kit if the nuclear pharmacist isn't available if a technologist can't come in yet. I know a

guy who used to run his own cameras by himself on call at night and do the whole thing himself.

I really believe that the emphasis should be completely on credentials in quantitative radiation protection plans. That's what you guys should all be doing. As soon as you start looking at medical qualifications, the hospital administrator says, "Oh, they've checked into that."

If you simply say outright, "We don't have anything to do with medical qualifications. Our job is to make sure the physicians are capable of intelligently handling, calculating, supervising radioactive material. We're going to stamp 'radionuclides' on the back of your license. We're not going to license you to practice any kind of medicine. We're just going to say you can be trusted to handle radioactive material. And the qualifications are going to be very substantial," that then has to put the burden of medical qualifications where it belongs. On practice privilege this committee is JCAHO oversight and gets you out of the loop that you don't want to be in.

This idea that the more hazardous the material you're dealing with the more education you need in science, that's not true. I taught basic radiation science for years. It's the same radiation decay

equation. It's the same internal dosimetry methodology. It's the same external dosimetry. It's the same inverse scalae. It's the same shielding calculation. It takes the same amount of time. Whether you apply it to microcuries, millicuries, or curies, it's the same basic science. It's the exact same math.

The physician has to know how to comply with Part 20 standards. And he has to have a certain basic skill in quantitative radiation science to do that.

FACILITATOR CAMERON: Okay. Carol, could you just --

DR. MARCUS: That ended it except for one last plea. And I really have to get this in. As we talk about the qualifications for physicians, some of the physicians really want to address the qualifications of the regulators at NRC because it is very difficult to find people in NMSS who understand quantitative radiation physics. And I ask that they be a little careful and make sure that they have people who can scientifically validate what they want us to do.

FACILITATOR CAMERON: Okay. I want to facilitate that meeting.

(Laughter.)

FACILITATOR CAMERON: Thank you, Carol.

Cathy, we're ready to move on into new thresholds or --

MS. HANEY: Well, can I talk two seconds on radiation safety officer? I'll do two minutes.

FACILITATOR CAMERON: Okay.

MS. HANEY: He just gave me two minutes. Let me just say that we did discuss the training for the radiation safety officer. We used the same approach as far as alternatives go that we use for the authorized user. It wouldn't be the same boards. It wouldn't be the same amount of training. But it was basically under the status quo. There's a certain Board certification or the hours plus a year experience under a radiation safety officer or you're an authorized user.

As I said earlier in response to Ed Bailey, the authorized user wouldn't automatically grant you RSO status any longer under Options 2 through 5 up there.

I think given time constraints, you probably don't have time to go through it all, but, again, the same philosophical approach. We would not list Board certifications any longer in the rule. We would say you've taken a Board certification that meets the B criteria. B would be the number of hours of training and experience.

The question comes up again: Can you do it with just: Is an exam needed? If you barely take a radiation safety exam, is that good enough to be a radiation safety officer or should it just be a certain amount of experience plus an exam?

So these are the alternatives that I'll lay out. I think I'll just go ahead and move on in to the other subject area, and you can --

FACILITATOR CAMERON: Yes. Why don't you do that? And I would ask if people want to talk to Cathy or Don specifically about this area, do that offline. And I think that a lot of the things that were said around the table also will apply to this area, too. So I think that we can move on to threshold. Go ahead.

MS. HANEY: Okay. Threshold of reportable events. I think the next two subject areas are a little bit on the controversial side also.

The working group ran into a slight problem on this particular item, and that is what we need to do to identify precursor events. Precursor events came up in the SRM that we got from the Commission.

The first question was: Define what a precursor event is. We kind of talked about it for a while. And then we got to the point where it's anything that you think we ought to know, you tell us.

(Laughter.)

MS. HANEY: And they said, "Cathy, that won't go in real language."

And I said, "You're right."

So we kind of wimped out a little bit. And we said, "Well, let's talk about what we want, what's intended by this precursor event." And some things that we came up with were events that would have programmatic implications for radiation safety.

We wanted to identify events, incidents, and situations which have implications at that facility or at other facilities of that type. The objective that we saw by the SRM direction to identify precursor events was to identify information that would be useful to avoid potentially significant problems and to approve radiation safety at licensed facilities.

That's as far as we got with defining precursor events. So if it does end up in the rule, we'll be back to you asking for help on how to define it in rule space. So, with that, we came back to: What options did we have under reportable events?

The first one was to go status quo plus this identification of precursors, "status quo" meaning that we kept the threshold for current misadministration and the threshold for current recordable events at the same level.

Option 2 was to raise the reportable to some percentage of the AO criteria, recognizing that we have to report certain events to Congress. And those are defined as abnormal occurrences. So we would pick some percentage of the AO criteria and then just raise the recordable level up.

The third option deletes the requirement for recordable events and also raises the recordable to this AO criteria.

The fourth option is a lowering of the reportable, which, in other words, the current misadministration criteria, to that of the current recordable plus its precursor.

And then the fifth alternative we came up with was any combination of 1, 2, 3, or 4, but, rather than a mandatory -- we covered all bases here -- rather than a mandatory requirement to report precursors to us, there would be some type of voluntary reporting system that was set up.

We presented this to the ACMUI. And they said, "Cathy, you left out one option."

And I was like, "Oh, no."

So there is an option between 1 and 2 that I think is worth mentioning at this point. That is that we would keep the current misadministration criteria as the

reportable criteria but the need for recordable be deleted.

Now, in the ACMUI's recommendation that we maintain the current misadministration criteria, there was a recognition that some of those criterias needed to be changed, for example, the dose to the wrong sites needed to be adjusted.

So we acknowledge that the current misadministration criteria isn't perfect and would need to be tweaked a little bit but that as an alternative for this threshold, that we just keep that misadministration.

Another thing is I've been using the term "misadministration," and Don is probably standing behind me giving me dirty looks.

FACILITATOR CAMERON: He is.

MS. HANEY: Okay. How did I know that?

FACILITATOR CAMERON: You could feel it, huh?

MS. HANEY: I've worked for him too long, I think.

We also had some direction that we should consider. Is "misadministration" the correct term? And the say, you know, you can come up with a better one. So we had the name an event contest. For the sake of getting these documents out, we're referring to it now as a medical event.

That is not etched in stone, by any means. So if you have a better name, I'm open to it. But realize by me using the "misadministration" term, I know that's another dirty word. But it will be changed.

FACILITATOR CAMERON: Okay. And, Cathy, in the interest of time and because this can quickly wrap into, as Don calls it, the next, in other words, do you need the report? Can you just put that up and go through there? And we'll come back and we'll do this discussion. And then we'll be all set.

MS. HANEY: All right. In reporting, obviously we have the requirement to report to Congress the abnormal occurrences. We also have a need to be reviewing events for their generic implications. But what this flows into is: At what point do we do patient notification?

Our options here were status quo, which was to notify NRC, notify the referring physician, which would result in a notification to the patient or responsible relative unless the referring physician says that it would be harmful to do so.

This was seen at the time when it came in as it was consistent with Parts 19 and 20 to tell the occupational worker when they have exceeded a dose limit. It was also seen as consistent with the Privacy Act for

the right of an individual to know information. And it also is consistent with NRC identifying precursor events as far as the report to NRC goes. But it's also been viewed as an unnecessary intrusion into the patient-physician relationship.

So, with that in mind, we went to: What were the alternatives? The first one was that licensee was to notify NRC. This does not mean that the licensee or the physician would not tell the patient. It's just the only thing in rule space would be: Tell us. Any further notification is up to the physician whether that's done or not.

And then we go from there to the licensee notifies NRC and the referring physician. Again, further notification to the patient is up to the physician. Under the fourth option, the licensee would always notify NRC, would always tell the referring physician, and would always tell the patient or guardian.

Now, we do recognize that this is definitely stepping in or could be viewed and probably definitely is stepping into the patient-physician relationship. But we put it up there as an option.

Recognize that we've now changed the term to "guardian" from "patient" and "responsible relative." We're using this term "guardian" very loosely right now.

It's meant to be the patient's next of kin, the person who has medical right of attorney, the legal guardian.

What it's not meant to be is the fifth cousin on the brother-in-law's side because we can't find anybody else to tell. So that may not be the right term, but for the sake of this discussion, we're going to use "guardian."

Now, the fifth option was to notify NRC, the referring physician, but only tell the patient if based on medical judgment there would be detrimental effects on the patient due to the reportable event.

This particular item brings in some problems because: How are you going to define "detrimental effect"? And also over what time period? Are we going to look at an effect over the next two weeks? Are we going to look at an effect over the next two years? So some of these options carry some baggage with them.

And they are all -- it's pretty much a tiered approach there as to how we go. And they are pretty closely tied to the previous conversation on the reporting threshold.

FACILITATOR CAMERON: Okay. Good. Why don't we put up the reporting threshold? And then we'll begin on this. As Cathy noted, there was a full range of options, at least an attempt to identify a full range of

options, so that the full range could be considered. They're not to be considered as proposals or recommended options from the NRC.

Who would like to start us off on the threshold issue? Anybody have any strong feelings? Is there an issue here about whether this is really a big deal or --

MS. ALLEN: This is Cathy Allen, Illinois.

I'm still -- I'm sorry -- a little confused with this precursor event thing. Do you have any more information on exactly how people are supposed to be tracking these?

MS. HANEY: We did not get into any sort of tracking on these other than to identify that if we truly got down at a very low level of risk associated with this precursor event, there could be an awful lot of reports that we were going to be receiving.

FACILITATOR CAMERON: Don?

DR. COOL: Perhaps it requires a little bit of elaboration. I can see that a little bit. Don't get so close to me, Chip.

FACILITATOR CAMERON: Ah. That's what causes it.

DR. COOL: That's what causes it.

The issue of precursor events is not a new issue for the Commission. It didn't get started in nuclear medicine. It sort of came there from other places. The whole issue comes about because of the desire by the agency, particularly looking at reactors and then looking at other kinds of things, to try and identify events before something big happens, which would allow you to understand and perhaps correct or provide information or do other things that would prevent the really difficult things from happening.

Now, most of the examples that tend to fly around the Commission are not medical examples, quite frankly. The one that I remember all too vividly because I was heavily involved in it about ten years ago but you can probably all relate to it, a large processing facility bulged a U.S. 6 cylinder when they overfilled it. They didn't break it. Nothing happened. They bulged a cylinder. And they didn't bother telling anybody about it.

All of this came to light about six months later or so, when the other facility down in Oklahoma blew the cylinder up. They did the exact same thing except they got a little more in it. It ruptured. It killed somebody, caused a whole lot of contamination and otherwise.

And that, in fact, was sort of one of the key items back about ten years ago, the start of the Commission on the road to looking for items which in and of themselves are not a great problem but which if knowledge of them is available to the community, then things could be taken or things could be watched for that might prevent other activities.

In this particular context, what has been talked about and certainly not nailed down in any sense, but the reason you've got something like perhaps an Alternative 5 is: Is there a set of things which if there were no repercussions associated with them would be useful to the industry as a whole in the context of a learning type of organization in order to improve the program's activities?

Now, many of them perhaps in this arena were pretty well-aware of its wrong syringes or its incorrect labels or there's a number of those human factor types of issues. But that's, in fact, what the Commission has asked us to explore, to what extent information of that type is useful before you get to something which is a violation or a significant error occurs in order to prevent those sorts of activities.

And that's why you see trying to find some sort of precursor and how you would attempt to identify it

is, quite frankly, a very difficult thing. We are looking for any sorts of advice as to how you would capture and to what extent you would use or what process you would use to capture it.

Does that help you a little bit, Cathy?

MS. ALLEN: Yes, it does, but it strikes me that you already appear to have a mechanism to do that without putting language in the rules. You learn about misadministrations or events, and you publicize this information widely. I would think that the regulatory community and the licensees are made aware of root causes for accidents and things that have happened.

And I know that when we have meetings with our licensees, we tell them war stories or give them advice about things that might be a problem. And I think there are organizations that meet, health physics societies, medical communities, that meet, and talk about problems and ways that they've resolved them.

I guess I'm not convinced of the need to have language in the rule that says, "And if we find something that would be helpful, we'll tell you."

FACILITATOR CAMERON: Does that suggest that -- there should be status quo without the precursor. Is that right?

MS. ALLEN: Right. I guess I'd like to see a 1.5 with no mention of precursors.

DR. COOL: Just to finish off that particular discussion, I think what the Commission really wanted the staff to at least explore -- and that's certainly a view which maybe we should take back to them. I think what they wanted us to explore was: Is there a way to capture a set of events before they actually got to misadministrations, which is where they're being captured now and being reported now?

FACILITATOR CAMERON: Okay. Steve? And I hope everybody understands the distinction there. I think we all do. Steve?

MR. COLLINS: Steve Collins from Illinois.

To follow up a little bit further with agreement with Cathy, I see this as two different things. And I would like to see part of the reportable stuff go away, as I stated earlier, for the medical policy statement, where that's not really messing into the practice of medicine and the physician-patient relationship.

But what I would like to see is, as health physicists in radiation safety issues, going back to something that's reportable only to the radiation regulatory agency. And that would be basically any time

you have a screw-up and you're not following your procedure properly and something goes wrong, you report to us and let us evaluate that from a health physics point of view and not base this strictly on: Did the patient get too much dose or something?

We've got two different things going here that are all mixed up together, and that causes part of the problem.

FACILITATOR CAMERON: Perhaps they have two different objectives or both of them have the same objective. I think that you flagged a point for us for the workshops. In other words, the value is not only to get the agreement state perspective, but this is sort of like playing off Broadway in a sense for us, a learning experience to go in and to make sure we have the best workshops.

The medical policy statement, as you pointed out, keeps coming up. And it came up in the training and experience area before. Maybe what we should do is when we present some of these alternatives later on, we should point out to people what the implications are of a revised medical policy statement.

At any rate, Aubrey?

MR. GODWIN: Whenever you present these, I'd suggest you have a package that slides abnormal occurrence

criteria because I'm not sure everybody's going to know that in the community. I think that would be good to have out to everybody.

Basically I'm not too interested in getting a lot of misadministration reports unless there's some way that it's exceeding like five rem to the individual or I certainly don't want to get all of these reports where they overdose somebody for one treatment and they corrected it over the next two or three treatments. I just don't see us in that business. That's a medical decision.

Now, if a doctor believes that there's a misadministration such that it went outside something, then I'd be happy to accept that. But anything less than five rem where there's exposure, I'm just not real sure I'd be very interested in it, which would take out just about everything in diagnostic and a good chunk of your therapeutic, particularly where they can correct it out over total dose considerations.

I'm not sure where precursor -- I still want to understand that.

FACILITATOR CAMERON: Okay. Thanks, Aubrey.

Stuart?

MR. LEVIN: Levin from Pennsylvania.

The precursor sounds to me like what I would call a near miss of a noncompliance of a regulation, which means you're in compliance but you almost were out of compliance. And we get occasional calls from our regulated community when something like that happens, but they know we're not going to run out and yell and scream at them and give them civil penalties and all that good stuff like other organizations might.

Near misses probably should be recorded. And somehow information disseminated so somebody else doesn't make the mistake, but you shouldn't be punished for doing a good deed.

FACILITATOR CAMERON: I don't know if this is reflected in our options, but the point that Steve made earlier about there may be a reason for knowing about this from another standpoint other than enforcement, I mean, delinking some of this from compliance might be very important.

How about patient notification? Roland?

MR. FLETCHER: Well, I guess it can be said sometimes bad memories outweigh enlightened regulatory changes. The problem, you know, I substitute in Maryland, where I see licensee to notify. And following looking at all options, I'm not sure the one that I fell into is even up there. And that is licensee would always notify

Maryland, the referring physician, and ensure that the patient is notified, not licensee notifies the patient.

And the reason that I even bring that up as a potential option is the fact that we have run into a situation where we've followed that very procedure. Licensee notified us. We ensured or at least got verbal assurance that the licensee notified the referring physician and verbal assurance that the patients were notified where that was possible.

But years later we were called to question for that very action. And no one could verify that the patient was actually ever notified. And it's a little -- you know, I'm a little uneasy with not having that complete closure.

FACILITATOR CAMERON: Okay. Thanks, Roland. That additional option will be captured.

Any other comments up here before we go to the audience about threshold or patient notification? Don, do you have a --

DR. COOL: Roland has brought up an interesting point. And so I want to toss it out as a question to the states just because there may well be some differences between federal law and state law.

One of the things that our General Counsel's Office is looking into for us right now is whether or not

there are, in fact, other federal statutes which, in essence, would dictate that there be some mechanism for the individual to know what the federal government knows.

This might become particularly important if you've reached the point where a report was going to be made to Congress that the individual knows what kind of information is being circulated around, being provided to Congress and otherwise.

My question to the states is whether there are similar sorts of things that you may be aware of within state statutes with regards to openness of information or notification of information which is contained in your system of records.

FACILITATOR CAMERON: I might ask Steve. The way that New York does this is different, and there are benefits to that.

MR. GAVITT: In New York, we have laws that protect patient privacy. And when NRC requests reports from us regarding misadministrations, we give the basic information. We do not identify facilities or obviously the patients.

FACILITATOR CAMERON: Okay. That's what I'm thinking. Thank you.

David?

MR. SNELLINGS: Yes. I want to go back to this threshold and reportability and such, --

FACILITATOR CAMERON: Okay. Good.

MR. SNELLINGS: -- if you don't mind.

FACILITATOR CAMERON: No. That's fine.

MR. SNELLINGS: I kind of agree with Aubrey that I don't think I want to know everything that happens, you know, all of these small things, but I think it's very important that the management of the facility know the goings-on. And this may be something that their radiation safety committee or the oversight committee should get involved with to fix the problem.

To me, you know, as you have these recurring events, -- and they could be precursors -- as you have these things, that is something that the management of the facility should definitely get involved in and fix because they can lead to bigger things.

I kind of go along with Aubrey that there should be some level of notification of the regulatory agency, as opposed to every small thing. We could then if the management -- and it's reported internally within that facility, we could then look at it during our regulatory inspection.

This kind of comes as a model from a former life. You know, nuclear power is very similar to doing this kind of thing.

FACILITATOR CAMERON: Thank you, David. That's instructive.

Aaron?

MR. PADGETT: I would just like to support that. Ten years ago at INPO, we were stressing very, very strongly the use of precursor events by the management in the facility. And I think the utilities have used those very well to cut dose and do other things like this.

I have some problem with them trying to capture them and report them up to the regulatory agency and this kind of thing. But the use of precursors by the management in the facility is an invaluable tool in improving your program.

MR. SNELLINGS: Most assuredly. Yes, it is.

FACILITATOR CAMERON: And that might be -- we were talking before about just setting functions or objectives for radiation safety committees. I suppose you could have some sort of a statement like that.

Is it too difficult to -- are there too many parameters connected to these options to get a feel for where all of you stand on this at this point? Probably need more information before you could say, "Well, we

definitely like Option 2" or "We definitely don't like Option 5," something like that? Okay. Cathy?

MS. HANEY: How about from the standpoint of let's say we do have to do something with precursor events because that's in the SRM that we're dealing with right now. Is there a feeling about whether it should be a voluntary report or a requirement for a report to us, the voluntary versus regulatory requirement, or, again, is it too early to ask that question or have I not --

FACILITATOR CAMERON: Or do we say that it's fine if the facility knows about the precursor events? Aaron, do you have any feel on that?

MR. PADGETT: Again, this is just one person's thoughts, but my thoughts are the facility ought to identify them. They ought to show that yes, we have looked at them, yes, we have used them when you're there on inspections. But as far as reporting them up the line, I really don't see a great deal of value in that.

There is some if there was a mechanism to then share them within the industry. I don't see that mechanism. And so I really right now don't see a lot of value in that.

MR. SNELLINGS: I think when you start sending them up the line, you're going to inhibit the reporting of them. I think that these precursors are small events that

could lead to something bigger. And you want them reported. Definitely management wants them reported so that they can then look at the big picture.

I don't see any reason to report them to you. I really don't.

MS. HANEY: Yes.

FACILITATOR CAMERON: Okay. Ed, one more comment on that before we go to the public. Ed?

MR. BAILEY: Yes. I can think of one example. And I haven't been close enough to it. So people can fill in. There was a time in nuclear medicine apparently one of the gallium and something else had very similar-colored labels on them. And there were several episodal events about where somebody grabbed something and thought they had something else just by the color.

Those kind of things I think got -- I don't know. Have they been corrected? Somebody that knows ought to --

DR. MARCUS: Yes.

FACILITATOR CAMERON: Okay. How about Bob Hallosay? All right.

MR. HALLOSAY: Hallosay from Massachusetts.

I wanted to address Don Cool's last question since he came back in the room. In our particular state, the Health Care Quality Group does address patient

notification and is sort of the group that follows HCFA requirements. So you may want to look in the HCFA area.

FACILITATOR CAMERON: Okay. HCFA being Health Care?

MR. HALLOSAY: Health Care Financing Administration.

FACILITATOR CAMERON: And they have requirements that deal with patient notification.

MR. HALLOSAY: At least in our state level, they do that.

FACILITATOR CAMERON: Okay. I mean, that's another option. Okay. Good. Thanks, Bob.

Going to the medical community, any comments on either threshold, patient notification? Could one of you give us sort of a -- yes?

DR. WEXLER: This regards this precursor business. I'm Marilyn Wexler, a medical physicist here in Los Angeles.

Most of you regulators don't work in hospitals and aren't real familiar with a lot of these programs that are ongoing that the Joint Commission of Hospital Accreditation forces these hospitals into.

We have millions of ways of reporting events. We have something called CQI, AQU. I mean, we have 30

different programs at work for us to document problem areas and ongoing audits of potential problem areas.

I would really urge the NRC to really look to the Joint Commission and see the programs they have in place now so that you don't duplicate what's going on. To think that a hospital is not undertaking a precursor issue area right now is crazy. They're looking at the stuff all the time. They're constantly being looked at. There are reams of paperwork being developed on a daily basis for this kind of stuff.

So I really hate to see the NRC spend my money, your time, and additional time on hospitals duplicating what's already being done. That's on precursors.

Number two, patient notification. This is an old pet peeve of mine. It's not even a pet peeve. I do a lot of medical malpractice reviews for radiation oncology problems. My husband is a radiation oncologist. There is no way that -- I work in radiation oncology. There is no way that I would ever expect to ask a physician to notify a patient by law or by NRC regulations of some kind of event that happened to that patient.

In surgery, the doctor is not required to notify the patient that he took out the wrong kidney even. That's called standards of practice, and it's also called

tort law. They take care of those issues. They're not being dictated by some regulatory agency at the state level or the federal level to notify a patient of anything.

I mean, I don't see where the NRC gets off thinking that they can force a physician to notify a patient of any kind of issues.

FACILITATOR CAMERON: That's a definite opinion. That's good.

(Laughter.)

FACILITATOR CAMERON: And I think you've raised an important point for us that often when we get to these workshops, what we want to know is: Is there something more that we need to know before we go ahead and regulate?

The need to know in this case would be the existing structure and system within the medical community, within the hospital for reporting events and precursors. I mean, before we make any decisions, we may, as you suggested, need to know that.

Carol?

DR. MARCUS: I think it's amusing that in one of NRC's recent regulatory guides, breast-feeding regulation, it says that you are forced to tell a breast-feeding mother what would happen to her baby if she

didn't stop breast-feeding. And you have to do this in writing. And if the answer is that there would be no effect on the baby at all, you have to do that in writing, too.

I mean, this is an example of the NRC being medically completely inappropriate and off the wall. I find, even in a county hospital, that the JCAHO requirements are huge for quality assurance. And sometimes a mistake here and there is not deemed a very important thing that issues of general quality in improvement of 9,999 patients and maybe one misadministration, it's much more important to improve the quality of those 9,999 patients.

So you again have a very narrow view of what quality really means. And I think that the medical institutions who have a broader view are much more appropriate and that I believe that the NRC should get completely out of this notification of patients routine. You have to notify patients because you'll get killed in court or your risk management people will chop you up if you try to hide things that have gone on.

As far as the threshold reports to the NRC are concerned, NRC only needs to know certain kinds of things. Ed mentioned the label colors as a problem. There was also a situation where Maryland Crouts technetium

generators were sitting outside of the airport in St. Louis and the columns froze and cracked. And then there was some moly leakage and stuff when people tried to aleut it.

To alert people that that batch has a problem because of that, this is what I consider to be a service to the public that NRC or an agreement state group can do. Everyone now has Web sites through the internet and fax machines. These facts tend to get known very, very quickly, though.

The first time a high-dose brachytherapy source broke off inside a patient, the NRC made a tremendous propaganda event out of that, but, believe me, the entire medical community communicated very quickly. Everybody who had those devices understood: number one, they can break; number two, that if the device reads that the source has been successfully retracted, don't believe it because the way it works is it goes by length, not by radiation detection, which is what happened in Indiana, Pennsylvania.

So I don't see that any real good is coming out of these reportable events to the NRC. I have seen embarrassing situations where the patient suddenly finds himself on the evening news, such as the situation that happened in Tripler, when a nurse breast-fed her baby

because she didn't tell her doctor she was breast-feeding. And she had some I-131 on board.

It was in the news. It was televised that night by the NRC. And this poor lady is in Honolulu. She must feel pretty bad. But to have it all over the television, where everybody knows who it has to be, I think is very bad form and as an example of how not to behave.

So I would limit the NRC to certain types of physics events or things that everyone ought to know about because it could help. And propaganda maybe is not the function of the NRC.

FACILITATOR CAMERON: Okay. Thank you, Carol. I think we would probably agree with that, --

(Laughter.)

FACILITATOR CAMERON: -- although we often don't recognize it when we see it or do it, I guess.

I think that we're at an end to this substantive session at this point. I just want to thank -- we're not at the end.

DR. WEXLER: Again, Marilyn Wexler from Los Angeles.

Ed Bailey at lunch asked me why I was so quiet because anybody who knows me knows I'm not quiet at these kinds of meetings. But just as a comment on the general

format of these kinds of meetings, this is my first visit to an NRC open meeting like this. I'm here as a representative from AAPM because I'm sitting on their committee to review the Part 35 revision.

And I'd like to say that one reason I have been quiet is because I was notified of this through the internet, not directly but somewhat. And I did not receive an agenda for this meeting. And I found myself ill-prepared really to comment on what we were going through because I wasn't aware of what exactly we were going to cover.

I also am aware of the fact that when people such as yourselves from the NRC, who have spent a lot of time trying to develop these proposed changes in Part 35, I know from my personal experience that at this point in the game I wouldn't blame you if you were somewhat resistant to taking suggestions from the audience, unconsciously, subconsciously, or even consciously.

I know that individuals who have spent 60, 80, or 100 hours on trying to get some kind of program together or changes in a policy are really a little bit resistant to hearing negative comments about that at this point.

I think it would have been a lot more productive if we professional organizations would have

been involved and medical organizations in a lot earlier stage of the game, not to say that we're not going to certainly be involved in it now, but I just know from my experience.

I've sat on a million committees. I've developed a million policies and procedures and programs. It's a lot harder to get comments through after the fact than during the very early developmental stages.

FACILITATOR CAMERON: Thanks for that, Marilyn. Hopefully we are trying to do that with the two workshops and all of the material that are on the internet. In fact, the associations have been heavily involved in that. This was sort of a strange meeting from that respect because it was part of the agreement states meeting.

Thank you for that. I wanted to thank you and all of the other people from the medical community who came and thank Carol Marcus for coordinating that.

Don Flater?

MR. FLATER: Again, I need to bring up something to be concerned about. We've been talking about hospitals. What about private practice? These thresholds of reportable events, nobody requires them to report anything to anybody.

And so don't just think that we have to deal with hospitals. We've got to deal with private practice. We've got to deal with the issue of clinics and some of those kinds of things. And with this outpatient care thing going on, the use of those kinds of institutions may well increase tremendously. So don't forget there's somebody besides hospitals out there.

FACILITATOR CAMERON: Okay. Cathy, you've got that. Thanks, Don. And I know that this part of the meeting is adjourned, and I know that you're going to go into a business meeting of sorts.

(Laughter.)

FACILITATOR CAMERON: I asked Bob if I could just say a few words from the facilitation standpoint before you got into that. And I think you may want to take a break.

I just wanted to say it was a real pleasure working with all of you again. I apologize that we did have a little problem running on schedule. And I probably could have been harder with some of the presenters. I think we got some good information out. Also I think suggestions for future agendas, maybe we try to do less and not feel so harried and perhaps have the time for some more quality discussions.

But the last thing I want to say is I think the taxpayers from your states should be really proud because you're a dedicated group to sit through all of the presentations. You were there. You were interested. You were commenting. I was really impressed by all of that. And I just wanted to leave you with that.

Thanks.

(Whereupon, the foregoing matter was concluded at 3:00 p.m.)