

# Official Transcript of Proceedings

## NUCLEAR REGULATORY COMMISSION

Title: 1997 All Agreement States Meeting  
Radiology Health Branch

Docket Number: (not applicable)

Location: Los Angeles, California

Date: Saturday, October 18, 1997

Work Order No.:NRC-1277

Pages 575-783

NOTE: The Table of Contents is not accurate. The individual page numbers are different from the original document and no longer match the Table of Contents because of the conversion to PDF.

NEAL R. GROSS AND CO., INC.  
Court Reporters and Transcribers  
1323 Rhode Island Avenue, N.W.  
Washington, D.C. 20005  
(202) 234-4433

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

UNITED STATES OF AMERICA  
NUCLEAR REGULATORY COMMISSION

+ + + + +

1997 ALL AGREEMENT STATES MEETING

+ + + + +

RADIOLOGY HEALTH BRANCH

+ + + + +

SATURDAY,

OCTOBER 18, 1997

+ + + + +

LOS ANGELES, CALIFORNIA

+ + + + +

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.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 ALSO PRESENT:  
2 CATHY ALLEN  
3 ED BAILEY  
4 MAX BATAVIA  
5 MIKE BRODERICK  
6 MARILYN C. WEXLER, M.S., DABR  
7 ROBERT E. CARRETTA, M.D., FACNP  
8 STEVE COLLINS  
9 VICK COOPER  
10 PAUL EASTVOLD  
11 JOHN ERIKSON  
12 DON FLATER  
13 ROLAND FLETCHER  
14 TERRY C. FRAZEE  
15 STEPHEN GAVITT  
16 AUBREY GODWIN  
17 BOB GOFF  
18 BOB HALLOSAY  
19 BRIAN HEARTY  
20 MIKE HENRY  
21 TOM HILL  
22 JAY HYLAND  
23 VICKIE JEFFS  
24 JOE KLINGER  
25 STUART LEVIN

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 ALSO PRESENT (CONT.):  
2 STAN MARSHALL  
3 RUTH McBURNEY  
4 JAMES L. McNEES, CHP  
5 MIKE MOBLEY  
6 AARON PADGETT  
7 RAY PARIS  
8 BILL PASSETTI  
9 TOM PATTERSON  
10 DAVID C. PRICE, M.D.  
11 BOB QUILLEN  
12 RICHARD RATLIFF  
13 ALICE ROGERS  
14 LYNN ROY  
15 BILL SINCLAIR  
16 DAVID SNELLINGS  
17 ROGER SUPPES  
18 DIANE TAFFT  
19 JARED THOMPSON  
20 DAVID WALTER  
21 KEN WANGLER  
22 RONNIE WASCOM  
23 KEN WEAVER  
24 KIRK WHATLEY  
25

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1  
2  
3  
4  
5  
6  
7  
8  
9  
10  
11  
12  
13  
14  
15  
16  
17  
18  
19  
20  
21  
22  
23  
24  
25

A-G-E-N-D-A

Agenda Item

---

Page

"Mini" Workshop: The NRC's Medical

581

Rulemaking Initiative

Dr. Don Cool, NMSS, NRC

Agreement State Participants

581

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

P-R-O-C-E-E-D-I-N-G-S

(8:30 a.m.)

1  
2  
3 FACILITATOR CAMERON: Well, good morning,  
4 everybody. Today we're going to focus. Hopefully we're  
5 going to focus shortly. We're going to focus on the NRC's  
6 rulemaking initiative on the regulations concerning the  
7 medical use of byproduct material.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

15           (Laughter.)

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

8           Our schedule, we're beginning at 8:30. We  
9 have until 2:15 today, perhaps a little bit longer. I  
10 don't know what the state of the agreement state business  
11 meeting is. But, at any rate, we have until approximately  
12 2:15.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

21           (Laughter.)

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

22 MS. ALLEN: Cathy Allen, State of Illinois.

23 MR. HENRY: Mike Henry for Louisiana.

24 MR. WEAVER: Ken Weaver, Colorado Public  
25 Health.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

6 MR. KLINGER: Joe Klinger, State of Illinois.

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

9 MR. TATE: Arthur Tate, State of Texas.

10 MR. GORDON: Craig Gordon, NRC.

11 MS. HOWARD: Marsha Howard, State of Ohio.

12 MR. WALTER: David Walter, State of Alabama.

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

16 MR. WRIGHT: Bill Wright, Arizona.

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

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

21 MR. HORNER: Jack Horner, NRC.

22 MS. McBURNEY: Ruth McBurney, State of Texas.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. EASTVOLD: Paul Eastvold, City of  
2 Illinois.

3 MR. OMO: Razor Omo, State of California.

4 MR. WOODRUFF: Richard Woodruff, NRC.

5 MS. HANEY: Cathy Haney, NRC.

6 MR. McNEES: Jim McNees, State of Alabama.

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

10 MS. ROY: Lynn Roy, California.

11 FACILITATOR CAMERON: Great.

12 MR. THOMPSON: Jared Thompson, Arkansas.

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

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

17 FACILITATOR CAMERON: California was good.

18 MR. SCOTT: Philip Scott, California.

19 MR. BATTELLE: Keith Battelle, California.

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

22 MR. ALAMO: Terry Alamo, California.

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

25 MR. VANGUARD: Richard Vanguard, NRC.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. LOHOUSE: Paul Lohouse, NRC.

2 MR. McDANIEL: Keith McDaniel, NRC.

3 MR. BALDMOY: Paul Baldmoy, DHS, California.

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

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

8 MR. FURY: Ken Fury, California.

9 MS. HENNER: Kathleen Henner, California.

10 MS. SCHNEIDER: Kathy Schneider, NRC.

11 MR. BOLLING: Lloyd Bolling, NRC.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

24           MR. BAILEY: Yes.

25           DR. COOL: Thank you.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

20                   MR. BAILEY: Bailey from California.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

7 Aubrey?

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 FACILITATOR CAMERON: Thanks, Don.

4 Mike Mobley?

5 MR. MOBLEY: Mike Mobley from Tennessee.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

10           When you have sample material sitting around  
11 in non-radiation arenas that's reading MR per hour levels  
12 for long periods of time, people are getting exposure to  
13 this. And you look at that, and you say, "Wait a minute.  
14 You know, if we were disposing of that as low-level waste,  
15 it would be over here. And you couldn't expose anybody in  
16 500 years to more than 25 millirem from that."

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

20           (Laughter.)

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

23           MR. MOBLEY: I do, and I will.

24           FACILITATOR CAMERON: Ray?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 FACILITATOR CAMERON: Okay. Thank you,  
4 Richard.

5 Steve?

6 MR. COLLINS: Steve Collins from Illinois.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

15           Aaron, do you have a comment?

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 DR. COOL: Welcome to the controversy.

2 MR. PADGETT: Right.

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

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

13 That construct is, in fact, limited to release  
14 of patients. It's why it's contained in the present Part  
15 35.75 and is not generally applicable to all of the other  
16 areas. I will tell you that there is a similar rule  
17 presently under consideration which would apply to  
18 individuals who would be visiting a patient in their rooms  
19 to have a matched construct in terms of that amount.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

13 I come back to the problem that Mike has. I'm  
14 also regulating, helping regulate, the development of a  
15 low-level waste site. And there we're seeing: Hey, if  
16 anybody out to 10,000 years at any point in time can get  
17 25 millirem, you can't open this site. Where is the  
18 logic?

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

13 DR. WHITE: Thank you very much.

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

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

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

25 (Laughter.)

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

15           Thank you very much.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

4           MR. FRAZEE: Terry Frazee, State of  
5 Washington.

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

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

17           So I think from my standpoint, the high risk,  
18 low risk, it's: Is real harm being done to a patient?  
19 And perhaps the guideline is LD<sub>50/30</sub>, you know, what's a  
20 lethal dose.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

4 FACILITATOR CAMERON: Okay. Thank you, Terry.

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

3 Cathy?

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 discussion needs it or if you want, basically you can tell  
2 me what one you want me to put on the screen.

3 Unfortunately, I don't have copies for you, but I'll be  
4 happy to go back to it.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 people think the policy statement needs to be changed?

2 Steve, you're reaching for your card.

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

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

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

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

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

23 MR. GODWIN: Probably not. Godwin, Arizona.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

20 But I do see that you need to sort of caveat  
21 that a little bit. So look at it. I guess it was Number  
22 2.

23 FACILITATOR CAMERON: Can we go to that Option  
24 2?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

13           FACILITATOR CAMERON: Okay. Thanks, Aubrey.

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

19           Ed?

20           MR. BAILEY: Bailey from California.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

17 Don, do you have a --

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

19 FACILITATOR CAMERON: Yes, sure.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

8 FACILITATOR CAMERON: Okay. Thank you.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

18           So, with that clarification, some other  
19 discussion.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

8           FACILITATOR CAMERON: Point well-taken.

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

8 Steve?

9 MR. COLLINS: Steve Collins, Illinois.

10 With this option, I would definitely be in  
11 favor of Option 1 and Option 3 and reversing the order of  
12 3 and 2. With regard to Number 2, Don Cool introduced by  
13 the way he phrased something earlier a confusion factor  
14 for me. And that's the meaning of "NRC will regulate the  
15 radiation safety of patients only" because earlier he made  
16 the statement that patients are a subset of members of the  
17 public.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

21 FACILITATOR CAMERON: Okay. Ken?

22 MR. WANGLER: Ken Wangler from North Dakota.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

19           MR. LEVIN: In my opinion, yes.

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

22           Tom?

23           MR. HILL: Tom Hill from Georgia.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

11 FACILITATOR CAMERON: Is that right? You like  
12 1 or 3? We're going to get into the numbers. I'm fairly  
13 confused now.

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

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

18 MR. LEVIN: That was in Option 2 --

19 MS. HANEY: Yes.

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

22 FACILITATOR CAMERON: Soon we'll be regulating  
23 --

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

10 FACILITATOR CAMERON: Fine with me.

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

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

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

16 FACILITATOR CAMERON: Option 3.

17 MS. HANEY: Option 3.

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

20 MS. HANEY: Okay.

21 FACILITATOR CAMERON: Okay.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

13 FACILITATOR CAMERON: Okay.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

8           Thank you.

9           FACILITATOR CAMERON: Thank you, Dr. Carretta.  
10           Terry?

11           MR. FRAZEE: Terry Frazee, Washington.

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

19           FACILITATOR CAMERON: Thank you. Thank you,  
20 Terry.

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

23           DR. PRICE: David Price from California.

24           I wanted to consider this scenario. A  
25 60-year-old man comes into the emergency room with chest

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

19 MR. FLETCHER: Roland Fletcher, Maryland.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

6 Thank you.

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

9 David?

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

7 FACILITATOR CAMERON: Okay. Thank you.  
8 Don?

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

17           FACILITATOR CAMERON: Thank you. Thank you,  
18 Ruth.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

17 MR. COLLINS: Option 2.

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

20 (Laughter.)

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

7 MS. HANEY: The one that states in --

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

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

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

22 MS. HANEY: Yes.

23 FACILITATOR CAMERON: Okay.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

22           FACILITATOR CAMERON: Okay. Thanks, Cathy.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

24 Bob?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

9 MS. MCBURNEY: Ruth.

10 FACILITATOR CAMERON: It's Ruth. Okay.

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

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

24 FACILITATOR CAMERON: Okay. Thanks, Ruth.

25 How about you, Aaron?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 Ed Bailey?

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

19 Don?

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 FACILITATOR CAMERON: Okay. Thanks, Don.

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

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

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

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

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

23 Terry?

24 MR. FRAZEE: Terry Frazee from Washington.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

23           FACILITATOR CAMERON: Okay. Thank you.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

20 MR. BAILEY: Can I make one thing?

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

23 MR. BAILEY: Yes.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

20 MR. GODWIN: That's right.

21 FACILITATOR CAMERON: Does that make sense?

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

17           (Laughter.)

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

8           FACILITATOR CAMERON: Okay. Thank you, Carol.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

14 MS. HANEY: Yes.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 Steve?

2 MR. COLLINS: Steve Collins from Illinois.

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

7 FACILITATOR CAMERON: Can you say who the --

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

10 FACILITATOR CAMERON: Could you just explain  
11 who --

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

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

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

21 FACILITATOR CAMERON: Okay.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 FACILITATOR CAMERON: David?

4 MR. WALTER: David Walter from Alabama.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

5 (Laughter.)

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

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

11 MR. COLLINS: Yes.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

13 FACILITATOR CAMERON: Okay. Thank you.

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

18 Ed?

19 MR. BAILEY: Bailey from California.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 FACILITATOR CAMERON: So that the --

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

12 (Laughter.)

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

18 Cathy, do you want to --

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 (Laughter.)

2 FACILITATOR CAMERON: Carol?

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

6           Thank you.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

23           Bob?

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

20 (Laughter.)

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 (Whereupon, there was a show of hands.)

4 MR. PADGETT: Clarification.

5 FACILITATOR CAMERON: Yes?

6 MR. PADGETT: Aaron Padgett, North Carolina.

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

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

16 (Whereupon, there was a show of hands.)

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

21 (Whereupon, there was a show of hands.)

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 FACILITATOR CAMERON: Okay.

2 MR. WHATLEY: Kirk Whatley.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

7           FACILITATOR CAMERON: Dr. Carretta?

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

23 Aaron, did you have a final comment or --

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

4 FACILITATOR CAMERON: Direct.

5 DR. CARRETTA: Direct.

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

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

11 MR. PADGETT: Thank you.

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

18 (Whereupon, a luncheon recess was taken.)  
19  
20  
21  
22  
23  
24

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

2 (1:00 p.m.)

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

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

12 Go ahead, Cathy.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 FACILITATOR CAMERON: Okay. Thanks, Cathy.

2 Again, if there are other alternatives, let's  
3 get those out on the table. These are all very specific  
4 options. Does someone have a context statement for this  
5 whole area? There have been a whole lot of references to  
6 training and experience this morning. Maybe I'm looking  
7 --

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

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

12 Yes, Cathy?

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

3 MR. GODWIN: Thank you.

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

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

14 (Laughter.)

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

19 FACILITATOR CAMERON: Don?

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

21           FACILITATOR CAMERON: Okay. Thank you.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

3 FACILITATOR CAMERON: Okay. Thank you.  
4 Stuart?

5 MR. LEVIN: Levin from Pennsylvania.

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

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

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

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

22 Steve Collins?

23 MR. COLLINS: Steve Collins, Illinois.

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

6 Cathy?

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

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

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

22 FACILITATOR CAMERON: Okay. So at the least  
23 --

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

9 FACILITATOR CAMERON: Okay. Thank you for  
10 that clarification.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

4                   (Laughter.)

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

7                   Ruth?

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 FACILITATOR CAMERON: Okay. Thank you.

2 Stan Marshall has had his card up for a while.

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

8 Ed?

9 MR. BAILEY: Bailey from California.

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

4           MS. HANEY: No.

5           FACILITATOR CAMERON: Okay. Clarify that for  
6 the transcript.

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

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

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

20           MS. HANEY: Yes.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

13 MR. WHATLEY: Kirk Whatley, Alabama.

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

24 Those are just some comments.

25 FACILITATOR CAMERON: Thanks, Kirk.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



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

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 given automatic privileges to perform all possible  
2 procedures.

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

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

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

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

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 radiation safety and other aspects of quality patient  
2 care. This approach also has the distinct advantage of  
3 utilizing existing entities at little or no additional  
4 cost.

5 Thank you.

6 MR. WANGLER: My name is Ken Wangler. I'm  
7 from North Dakota.

8 JCAHO, maybe you could explain that a little  
9 bit because I know that not all hospitals are a member of  
10 that or participate in that.

11 DR. COHEN: If you want to be reimbursed by  
12 Medicare, Medicaid, and most insurance companies, you must  
13 be accredited by the Joint Commission on Accreditation of  
14 Health Care Organizations. They now also monitor  
15 outpatient facilities and have a separate manual on  
16 outpatient faculties, where it used to only be hospitals.

17 FACILITATOR CAMERON: I want to go back to you  
18 to get some questions or comments on Dr. Cohen's  
19 presentation, but I really would like to get Lynn Roy up  
20 here to give us her perspective on this. So then we'll  
21 have it all.

22 MR. FLATER: I just want to clarify the  
23 doctor's statement. I'm sorry to disagree with him, but,  
24 at least in the State of Iowa, probably two-thirds of our  
25 hospitals do not belong to JCAHO. They are accredited by

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 the State of Iowa, by the Medicare body within the state.  
2 So you do not have to be accredited by them.

3 FACILITATOR CAMERON: I think that Dr. Cohen  
4 did mention state licensing boards, but a good point.

5 Lynn?

6 MS. ROY: Nuclear medicine is just not about  
7 injecting and handling radioactive materials. That's not  
8 why it exists. It's about providing information to  
9 physicians to treat a patient with the desire to make them  
10 better.

11 You can have perfectly wonderful safe handling  
12 of radioactive substance. And if the study isn't  
13 performed appropriately and if it's not interpreted  
14 appropriately, you can have far more poor outcomes than if  
15 you injected a higher or lower dose. And I don't have to  
16 waste anybody's time in describing that. It's a process.  
17 And you cannot take apart each process. You can, but  
18 you're not accomplishing anything.

19 Nuclear medicine technologists, -- and I think  
20 the gentleman over here is correct -- we either prepare  
21 radiopharmaceuticals if we're not getting them from a  
22 radiopharmacy or we get them from a radiopharmacy, we  
23 calibrate them, and we inject them. We do this from an  
24 order from a physician.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           After we do that, we have to image the  
2 patient. And there are all kinds of techniques and all  
3 kinds of positioning that you have to go through to get  
4 that. You develop the film, and then you give it to the  
5 physician to interpret.

6           There is a very strong correlation with the  
7 success of that whole process with the education and the  
8 training of a nuclear medicine technologist and the  
9 physician. The technologist section strongly supports  
10 certification and licensure, so much so that we've joined  
11 forced with the ASRT to try to get the Randolph bill,  
12 which was enacted in 1981, which required states to have  
13 technologists using ionizing radiation to have licensing,  
14 which requires education.

15           There are two credentialing boards currently  
16 in nuclear medicine: the ARRT and the NMTCB. To have to  
17 get one of these, to be accredited by them, you have to  
18 graduate from a school that is accredited. These schools  
19 offer many, many hours in radiation safety, proper  
20 handling of radiopharmaceuticals, and everything else that  
21 goes into nuclear medicine.

22           I don't believe and the technologist section  
23 does not believe that the NRC should be involved in  
24 setting those standards. I don't believe they have the  
25 experience in deciding how many hours of biochemistry,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 physiology, and anatomy that a nuclear medicine  
2 technologist needs to take. They don't do that for  
3 physicians.

4           However, if the NRC is interested in assuring  
5 that only educated, well-trained technologists do perform  
6 these procedures, we would like to invite you to join with  
7 us in assuring that the Randolph bill or something very  
8 similar is enacted so we can assure that we have  
9 qualified, well-trained technologists working doing  
10 nuclear medicine procedures.

11           Thank you.

12           FACILITATOR CAMERON: Thank you very much,  
13 Lynn.

14           I'd like to hear some reactions around the  
15 table to what we've just heard and try to tie some of this  
16 together. David, you have been there for a while. Do you  
17 want to make a comment before we go back up here?

18           MR. WALTER: Yes. This is David Walter from  
19 Alabama.

20           A number of the states that are represented  
21 here today already have required technologist  
22 certification programs. Unfortunately, that's a minority  
23 at this point.

24           One of the things that the CRCPD group or  
25 part, key group, is going to talk about on Monday and

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Tuesday of this week here in L.A. is a minimum training  
2 and experience qualification criteria for technologists to  
3 be added into the Part B suggested state regulations.

4           We've known that this has been a problem for a  
5 long time. We just had not really acted on it on a  
6 national scale. And a number of states took the  
7 initiative to go ahead and do this on their own.

8           We are drawing from those states and their  
9 experiences in this to try and put together as good a  
10 program as we can to be put into the rules. So we're  
11 going that direction. All right? That's the first thing.

12           The second thing, earlier today we heard about  
13 the presence of the physician, the authorized user, in the  
14 facility for whatever study is going to be done. And with  
15 the growth in teleradiology, it's just not going to  
16 happen.

17           I don't care what happens with HCFA right now.  
18 I know that it won't last. It's not going to be approved.  
19 I can't see it being approved that they turn down the  
20 payment of a diagnostic nuclear medicine study via  
21 teleradiology simply because the physician wasn't there.

22           So we need to be able to take that into  
23 consideration also when we go through our training and  
24 experience requirements for someone being on site if  
25 necessary.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 FACILITATOR CAMERON: Thank you, David.

2 Does anybody want to pick up on Dr. Cohen or  
3 Lynn Roy, on their presentation?

4 MR. COLLINS: Steve Collins, Illinois.

5 Illinois is one of the states that does, in  
6 fact, have test accreditation requirements. We recognize  
7 both testing by the two organizations she mentioned as  
8 meeting our requirements. The only thing we have on that  
9 is CEU credits, a certain number of hours to maintain  
10 that. So we do believe that's necessary and have adopted  
11 that. And we think for those people who are the ones  
12 using the material, that's the right way to go.

13 In that context, that's the reason that we can  
14 say if the physician is not going to be there in the room  
15 when use of radioactive material is going on, then we're  
16 not sure you need the physician as an authorized user if  
17 the medical policy is changed to say, "We don't get  
18 involved in the practice of medicine."

19 If it's only going to be radiation safety,  
20 then we're not sure if the physician is not going to be  
21 there that they need to be tested or anything else. So  
22 one of your options that's not there is: Who cares in  
23 that particular case? But there's a whole set of ifs that  
24 go into that qualifying statement.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           With regard to the practice of medicine, one  
2 of the problems we get into is the fact that most of us  
3 don't believe that the boards of medicine or the physician  
4 professional organizations have or are, in fact, going to  
5 be able to limit the practice in those fields of medicine  
6 to those people who are really qualified. If, in fact,  
7 they could describe how they are going to accomplish that,  
8 then we can back totally out of it and look only at the  
9 radiation safety aspect and simplify this whole thing.

10           FACILITATOR CAMERON: I think that clears a  
11 lot of the confusion up, at least for me.

12           I want to quickly go through the cards and the  
13 people in the audience because we do have to move on to  
14 the next area now. Let's start with Bailey and then  
15 Quillen right here and then go on down the line and go  
16 back to Arkansas and Carol Marcus.

17           MR. BAILEY: California is also one of those  
18 states that requires certification of the technologists.  
19 And I would agree with everything that's been said about  
20 the importance of the technologists being trained and  
21 receiving continuing education. I think it's been a great  
22 benefit.

23           I guess putting back on my regulator's hat a  
24 little bit, it also has enabled us in several situations  
25 in this state to basically fix blame where blame belonged,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 where a patient was stuck with a needle that had already  
2 been used on an HIV patient, where the wrong patient was  
3 injected with labeled white blood cells. It wasn't  
4 anything that the doctor had to do with that. It was a  
5 technologist who wasn't being very conscientious about  
6 what they were looking at.

7 I still have some problem with in any way  
8 allowing the doctors to get out of any responsibility  
9 because in California, there are one of two  
10 entrepreneurial types. I can tell you that if you don't  
11 have the doctor very, very closely and legally tied to  
12 this operation, you're going to see what we have seen in  
13 some cases where a tech buys a machine and he goes out and  
14 he contracts with somebody to do something. And there are  
15 people whose primary concern is not the health and welfare  
16 of patients. And their primary concern appears to be  
17 making money.

18 I think it's a very important team. And both  
19 of them have to be recognized and held accountable for  
20 what they do.

21 FACILITATOR CAMERON: Okay. Thank you, Ed.  
22 Bob?

23 MR. QUILLEN: Quillen, Colorado.

24 My comment's based upon roughly 12 years of  
25 working in a teaching hospital. From that experience, I

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 would say from a personal point of view, as far as the  
2 physician is concerned, I am most interested in their  
3 qualifications as a physician, not as a radiation safety  
4 expert.

5           One indication of that is: Do they have Board  
6 certification? So when I look at a physician, I look for  
7 the Board certification. This is a personal preference.

8           But the physician is not the person who is  
9 handling the radioactive material except in very rare  
10 cases. It's the technologist who is handling the  
11 radioactive material. And under the current scheme, we do  
12 not look at the technologist. We do not evaluate the  
13 technologist.

14           Colorado does have and has had certification  
15 requirements for mammography technologists before in the  
16 U.S.A. That's because we had one state legislator who was  
17 very interested in that topic, but we don't have that for  
18 nuclear medicine. And this is the missing link in this  
19 whole issue of training and experience.

20           FACILITATOR CAMERON: So some states, Illinois  
21 does have requirements, but most states do not. Okay.

22           Aaron?

23           MR. PADGETT: I'll see if I can muddy the  
24 water just a little more. Aaron Padgett, North Carolina.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           We at one time had a rule that said the  
2 physician had to be in the facility where the patient was  
3 being treated. There was a bright, young female physician  
4 who said, "Up yours."

5           So being good bureaucrats, we said, "You'll do  
6 it our way or you won't do it."

7           Well, when the judge looked down from his  
8 podium and said, "Mr. Radiation Protection, where is your  
9 medical degree that allows you to tell her how to practice  
10 medicine?"; essentially, we lost the case. So there's  
11 probably a player here that we have not talked about yet,  
12 and that's the Bar Association and the local judges, as we  
13 found out.

14           MR. BAILEY: Can I just make one quick  
15 response to that?

16           FACILITATOR CAMERON: Yes.

17           MR. BAILEY: As much as I hate to admit it and  
18 I wish that weren't on the record now, there is some  
19 advantage to being in health departments because when they  
20 come out from a health department, in general you have  
21 somebody that is the state health officer and that judge  
22 loses his argument because I can guarantee you that when  
23 we take an action against a hospital or a doctor, there's  
24 going to be somebody in my department that is going to  
25 say, "Now, is this really necessary?" They'll usually

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 support you all the way up, but they'll look at it closely  
2 before they will agree that you're going to do something  
3 real drastic.

4 FACILITATOR CAMERON: Okay. Thank you. Thank  
5 you, Ed.

6 Ruth?

7 MS. McBURNEY: Just to speak to the  
8 technologist issue. And this also came up at the ACMUI  
9 meeting. We in Texas felt that it was so important -- we  
10 have not put it into our regulations yet, but we did form  
11 a consensus group that was made up of technologists,  
12 nuclear pharmacists, and radiation safety officers at  
13 medical facilities, and some of our regulatory staff to  
14 come up with what would be the minimum criteria for the  
15 technologists. We are putting that into our regulatory  
16 guide as acceptable training and experience for the  
17 technologists in licensing medical facilities.

18 Now, I've given that information to Cathy for  
19 the working group's consideration.

20 FACILITATOR CAMERON: Okay. Thank you, Ruth.

21 Don?

22 DR. COOL: Just a quick point. And it's  
23 something that seems to be going at least in the rural  
24 areas. And that is what is allowed for a physician's  
25 assistant to do? They are ordering nuclear med exams,

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 those kinds of things, already. And we're seeing them  
2 specialize in other areas.

3 So I don't know whether they're going to come  
4 into the radiology area or not, but at one time Kentucky  
5 had a school that they were training them to be  
6 physician's assistants in radiology. That may be another  
7 area because those people certainly are not M.D.'s.

8 FACILITATOR CAMERON: Okay. Thanks, Don.

9 I just wanted to get a clarification from Lynn  
10 Roy. You heard Illinois talk about their requirements.  
11 Is that something that the technologists support or don't  
12 support? I was just trying to get a feeling for how the  
13 industry -- could you just speak into the mike? I don't  
14 want to delay things here, but I was a little bit confused  
15 about that.

16 MS. ROY: The end result obviously is  
17 competency because you can take all the tests in the world  
18 and have all the CME credits in the world and not  
19 particularly be competent, but there's only so much anyone  
20 can do. So one would assume that if you had so many hours  
21 and so many topics and passed the test, that yes, you are  
22 competent.

23 We would like to have people take recognized  
24 national tests, such as the NMTCB and ARRT, but we would

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 also support -- and it would depend on how each state  
2 structured their own particular exam.

3           The State of California, where I happened to  
4 be in, they recognize the NMTCB. You also can take the  
5 state license test in nuclear medicine in California, but  
6 it's very, very similar to the NMTCB. So we would support  
7 that.

8           What we do want is to have certified, trained  
9 individuals because that is going to assure better  
10 outcomes. And how that is accomplished, it's probably not  
11 as important as: Is it accomplished?

12           Sometimes the means overwhelm the end. And I  
13 think we need to look at the whole process and outcomes  
14 and: What do we really want to gain here?

15           FACILITATOR CAMERON: Okay. Thank you. Thank  
16 you very much.

17           Jared and Carol, I'm going to have to ask you  
18 to be real quick because we've got to move. Jared?

19           MR. THOMPSON: Jared Thompson in Arkansas.

20           As a license reviewer, this is one of the  
21 things that gives me the most heartburn: reviewing  
22 physicians' credentials. I detest calling a physician and  
23 telling him that he's not qualified. It makes my upper  
24 management real nervous. They squirm.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And I can't see offering an exam and saying,  
2 "Hey, doc, by the way, you also failed your radiation  
3 safety exam."

4           (Laughter.)

5           MR. THOMPSON: Things need to be simplified as  
6 simply as possible to keep us as licensing people out of  
7 that situation of trying to tell docs whether they're  
8 qualified or not.

9           FACILITATOR CAMERON: Okay. Thanks. That's  
10 sort of a good thing to have on the record at the end.

11           Carol?

12           DR. MARCUS: A couple of things. First of  
13 all, please understand that under every state's malpractice  
14 law, the physician is ultimately responsible for the  
15 quality of the medical practice that takes place under his  
16 responsibility. While you may look at whether it's the  
17 tech or the doc, in court it's the doc.

18           Number two, physicians handle radioactive  
19 material and inject patients all the time. You may not  
20 see it. I inject patients all of the time. Please  
21 understand that physicians have to know how to handle  
22 radioactive material.

23           Some places the physicians will milk a  
24 generator or make up a kit if the nuclear pharmacist isn't  
25 available if a technologist can't come in yet. I know a

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 guy who used to run his own cameras by himself on call at  
2 night and do the whole thing himself.

3 I really believe that the emphasis should be  
4 completely on credentials in quantitative radiation  
5 protection plans. That's what you guys should all be  
6 doing. As soon as you start looking at medical  
7 qualifications, the hospital administrator says, "Oh,  
8 they've checked into that."

9 If you simply say outright, "We don't have  
10 anything to do with medical qualifications. Our job is to  
11 make sure the physicians are capable of intelligently  
12 handling, calculating, supervising radioactive material.  
13 We're going to stamp 'radionuclides' on the back of your  
14 license. We're not going to license you to practice any  
15 kind of medicine. We're just going to say you can be  
16 trusted to handle radioactive material. And the  
17 qualifications are going to be very substantial," that  
18 then has to put the burden of medical qualifications where  
19 it belongs. On practice privilege this committee is JCAHO  
20 oversight and gets you out of the loop that you don't want  
21 to be in.

22 This idea that the more hazardous the material  
23 you're dealing with the more education you need in  
24 science, that's not true. I taught basic radiation  
25 science for years. It's the same radiation decay

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 equation. It's the same internal dosimetry methodology.  
2 It's the same external dosimetry. It's the same inverse  
3 scalae. It's the same shielding calculation. It takes  
4 the same amount of time. Whether you apply it to  
5 microcuries, millicuries, or curies, it's the same basic  
6 science. It's the exact same math.

7           The physician has to know how to comply with  
8 Part 20 standards. And he has to have a certain basic  
9 skill in quantitative radiation science to do that.

10           FACILITATOR CAMERON: Okay. Carol, could you  
11 just --

12           DR. MARCUS: That ended it except for one last  
13 plea. And I really have to get this in. As we talk about  
14 the qualifications for physicians, some of the physicians  
15 really want to address the qualifications of the  
16 regulators at NRC because it is very difficult to find  
17 people in NMSS who understand quantitative radiation  
18 physics. And I ask that they be a little careful and make  
19 sure that they have people who can scientifically validate  
20 what they want us to do.

21           FACILITATOR CAMERON: Okay. I want to  
22 facilitate that meeting.

23           (Laughter.)

24           FACILITATOR CAMERON: Thank you, Carol.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Cathy, we're ready to move on into new  
2 thresholds or --

3 MS. HANEY: Well, can I talk two seconds on  
4 radiation safety officer? I'll do two minutes.

5 FACILITATOR CAMERON: Okay.

6 MS. HANEY: He just gave me two minutes. Let  
7 me just say that we did discuss the training for the  
8 radiation safety officer. We used the same approach as  
9 far as alternatives go that we use for the authorized  
10 user. It wouldn't be the same boards. It wouldn't be the  
11 same amount of training. But it was basically under the  
12 status quo. There's a certain Board certification or the  
13 hours plus a year experience under a radiation safety  
14 officer or you're an authorized user.

15 As I said earlier in response to Ed Bailey,  
16 the authorized user wouldn't automatically grant you RSO  
17 status any longer under Options 2 through 5 up there.

18 I think given time constraints, you probably  
19 don't have time to go through it all, but, again, the same  
20 philosophical approach. We would not list Board  
21 certifications any longer in the rule. We would say  
22 you've taken a Board certification that meets the B  
23 criteria. B would be the number of hours of training and  
24 experience.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The question comes up again: Can you do it  
2 with just: Is an exam needed? If you barely take a  
3 radiation safety exam, is that good enough to be a  
4 radiation safety officer or should it just be a certain  
5 amount of experience plus an exam?

6           So these are the alternatives that I'll lay  
7 out. I think I'll just go ahead and move on in to the  
8 other subject area, and you can --

9           FACILITATOR CAMERON: Yes. Why don't you do  
10 that? And I would ask if people want to talk to Cathy or  
11 Don specifically about this area, do that offline. And I  
12 think that a lot of the things that were said around the  
13 table also will apply to this area, too. So I think that  
14 we can move on to threshold. Go ahead.

15           MS. HANEY: Okay. Threshold of reportable  
16 events. I think the next two subject areas are a little  
17 bit on the controversial side also.

18           The working group ran into a slight problem on  
19 this particular item, and that is what we need to do to  
20 identify precursor events. Precursor events came up in  
21 the SRM that we got from the Commission.

22           The first question was: Define what a  
23 precursor event is. We kind of talked about it for a  
24 while. And then we got to the point where it's anything  
25 that you think we ought to know, you tell us.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 (Laughter.)

2 MS. HANEY: And they said, "Cathy, that won't  
3 go in real language."

4 And I said, "You're right."

5 So we kind of wimped out a little bit. And we  
6 said, "Well, let's talk about what we want, what's  
7 intended by this precursor event." And some things that  
8 we came up with were events that would have programmatic  
9 implications for radiation safety.

10 We wanted to identify events, incidents, and  
11 situations which have implications at that facility or at  
12 other facilities of that type. The objective that we saw  
13 by the SRM direction to identify precursor events was to  
14 identify information that would be useful to avoid  
15 potentially significant problems and to approve radiation  
16 safety at licensed facilities.

17 That's as far as we got with defining  
18 precursor events. So if it does end up in the rule, we'll  
19 be back to you asking for help on how to define it in rule  
20 space. So, with that, we came back to: What options did  
21 we have under reportable events?

22 The first one was to go status quo plus this  
23 identification of precursors, "status quo" meaning that we  
24 kept the threshold for current misadministration and the  
25 threshold for current recordable events at the same level.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           Option 2 was to raise the reportable to some  
2 percentage of the AO criteria, recognizing that we have to  
3 report certain events to Congress. And those are defined  
4 as abnormal occurrences. So we would pick some percentage  
5 of the AO criteria and then just raise the recordable  
6 level up.

7           The third option deletes the requirement for  
8 recordable events and also raises the recordable to this  
9 AO criteria.

10           The fourth option is a lowering of the  
11 reportable, which, in other words, the current  
12 misadministration criteria, to that of the current  
13 recordable plus its precursor.

14           And then the fifth alternative we came up with  
15 was any combination of 1, 2, 3, or 4, but, rather than a  
16 mandatory -- we covered all bases here -- rather than a  
17 mandatory requirement to report precursors to us, there  
18 would be some type of voluntary reporting system that was  
19 set up.

20           We presented this to the ACMUI. And they  
21 said, "Cathy, you left out one option."

22           And I was like, "Oh, no."

23           So there is an option between 1 and 2 that I  
24 think is worth mentioning at this point. That is that we  
25 would keep the current misadministration criteria as the

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 reportable criteria but the need for recordable be  
2 deleted.

3           Now, in the ACMUI's recommendation that we  
4 maintain the current misadministration criteria, there was  
5 a recognition that some of those criterias needed to be  
6 changed, for example, the dose to the wrong sites needed  
7 to be adjusted.

8           So we acknowledge that the current  
9 misadministration criteria isn't perfect and would need to  
10 be tweaked a little bit but that as an alternative for  
11 this threshold, that we just keep that misadministration.

12           Another thing is I've been using the term  
13 "misadministration," and Don is probably standing behind  
14 me giving me dirty looks.

15           FACILITATOR CAMERON: He is.

16           MS. HANEY: Okay. How did I know that?

17           FACILITATOR CAMERON: You could feel it, huh?

18           MS. HANEY: I've worked for him too long, I  
19 think.

20           We also had some direction that we should  
21 consider. Is "misadministration" the correct term? And  
22 the say, you know, you can come up with a better one. So  
23 we had the name an event contest. For the sake of getting  
24 these documents out, we're referring to it now as a  
25 medical event.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           That is not etched in stone, by any means. So  
2 if you have a better name, I'm open to it. But realize by  
3 me using the "misadministration" term, I know that's  
4 another dirty word. But it will be changed.

5           FACILITATOR CAMERON: Okay. And, Cathy, in  
6 the interest of time and because this can quickly wrap  
7 into, as Don calls it, the next, in other words, do you  
8 need the report? Can you just put that up and go through  
9 there? And we'll come back and we'll do this discussion.  
10 And then we'll be all set.

11           MS. HANEY: All right. In reporting,  
12 obviously we have the requirement to report to Congress  
13 the abnormal occurrences. We also have a need to be  
14 reviewing events for their generic implications. But what  
15 this flows into is: At what point do we do patient  
16 notification?

17           Our options here were status quo, which was to  
18 notify NRC, notify the referring physician, which would  
19 result in a notification to the patient or responsible  
20 relative unless the referring physician says that it would  
21 be harmful to do so.

22           This was seen at the time when it came in as  
23 it was consistent with Parts 19 and 20 to tell the  
24 occupational worker when they have exceeded a dose limit.  
25 It was also seen as consistent with the Privacy Act for

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 the right of an individual to know information. And it  
2 also is consistent with NRC identifying precursor events  
3 as far as the report to NRC goes. But it's also been  
4 viewed as an unnecessary intrusion into the  
5 patient-physician relationship.

6           So, with that in mind, we went to: What were  
7 the alternatives? The first one was that licensee was to  
8 notify NRC. This does not mean that the licensee or the  
9 physician would not tell the patient. It's just the only  
10 thing in rule space would be: Tell us. Any further  
11 notification is up to the physician whether that's done or  
12 not.

13           And then we go from there to the licensee  
14 notifies NRC and the referring physician. Again, further  
15 notification to the patient is up to the physician. Under  
16 the fourth option, the licensee would always notify NRC,  
17 would always tell the referring physician, and would  
18 always tell the patient or guardian.

19           Now, we do recognize that this is definitely  
20 stepping in or could be viewed and probably definitely is  
21 stepping into the patient-physician relationship. But we  
22 put it up there as an option.

23           Recognize that we've now changed the term to  
24 "guardian" from "patient" and "responsible relative."  
25 We're using this term "guardian" very loosely right now.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 It's meant to be the patient's next of kin, the person who  
2 has medical right of attorney, the legal guardian.

3           What it's not meant to be is the fifth cousin  
4 on the brother-in-law's side because we can't find anybody  
5 else to tell. So that may not be the right term, but for  
6 the sake of this discussion, we're going to use  
7 "guardian."

8           Now, the fifth option was to notify NRC, the  
9 referring physician, but only tell the patient if based on  
10 medical judgment there would be detrimental effects on the  
11 patient due to the reportable event.

12           This particular item brings in some problems  
13 because: How are you going to define "detrimental  
14 effect"? And also over what time period? Are we going to  
15 look at an effect over the next two weeks? Are we going  
16 to look at an effect over the next two years? So some of  
17 these options carry some baggage with them.

18           And they are all -- it's pretty much a tiered  
19 approach there as to how we go. And they are pretty  
20 closely tied to the previous conversation on the reporting  
21 threshold.

22           FACILITATOR CAMERON: Okay. Good. Why don't  
23 we put up the reporting threshold? And then we'll begin  
24 on this. As Cathy noted, there was a full range of  
25 options, at least an attempt to identify a full range of

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 options, so that the full range could be considered.  
2 They're not to be considered as proposals or recommended  
3 options from the NRC.

4           Who would like to start us off on the  
5 threshold issue? Anybody have any strong feelings? Is  
6 there an issue here about whether this is really a big  
7 deal or --

8           MS. ALLEN: This is Cathy Allen, Illinois.

9           I'm still -- I'm sorry -- a little confused  
10 with this precursor event thing. Do you have any more  
11 information on exactly how people are supposed to be  
12 tracking these?

13           MS. HANEY: We did not get into any sort of  
14 tracking on these other than to identify that if we truly  
15 got down at a very low level of risk associated with this  
16 precursor event, there could be an awful lot of reports  
17 that we were going to be receiving.

18           FACILITATOR CAMERON: Don?

19           DR. COOL: Perhaps it requires a little bit of  
20 elaboration. I can see that a little bit. Don't get so  
21 close to me, Chip.

22           FACILITATOR CAMERON: Ah. That's what causes  
23 it.

24           DR. COOL: That's what causes it.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The issue of precursor events is not a new  
2 issue for the Commission. It didn't get started in  
3 nuclear medicine. It sort of came there from other  
4 places. The whole issue comes about because of the desire  
5 by the agency, particularly looking at reactors and then  
6 looking at other kinds of things, to try and identify  
7 events before something big happens, which would allow you  
8 to understand and perhaps correct or provide information  
9 or do other things that would prevent the really difficult  
10 things from happening.

11           Now, most of the examples that tend to fly  
12 around the Commission are not medical examples, quite  
13 frankly. The one that I remember all too vividly because  
14 I was heavily involved in it about ten years ago but you  
15 can probably all relate to it, a large processing facility  
16 bulged a U.S. 6 cylinder when they overfilled it. They  
17 didn't break it. Nothing happened. They bulged a  
18 cylinder. And they didn't bother telling anybody about  
19 it.

20           All of this came to light about six months  
21 later or so, when the other facility down in Oklahoma blew  
22 the cylinder up. They did the exact same thing except  
23 they got a little more in it. It ruptured. It killed  
24 somebody, caused a whole lot of contamination and  
25 otherwise.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           And that, in fact, was sort of one of the key  
2 items back about ten years ago, the start of the  
3 Commission on the road to looking for items which in and  
4 of themselves are not a great problem but which if  
5 knowledge of them is available to the community, then  
6 things could be taken or things could be watched for that  
7 might prevent other activities.

8           In this particular context, what has been  
9 talked about and certainly not nailed down in any sense,  
10 but the reason you've got something like perhaps an  
11 Alternative 5 is: Is there a set of things which if there  
12 were no repercussions associated with them would be useful  
13 to the industry as a whole in the context of a learning  
14 type of organization in order to improve the program's  
15 activities?

16           Now, many of them perhaps in this arena were  
17 pretty well-aware of its wrong syringes or its incorrect  
18 labels or there's a number of those human factor types of  
19 issues. But that's, in fact, what the Commission has  
20 asked us to explore, to what extent information of that  
21 type is useful before you get to something which is a  
22 violation or a significant error occurs in order to  
23 prevent those sorts of activities.

24           And that's why you see trying to find some  
25 sort of precursor and how you would attempt to identify it

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 is, quite frankly, a very difficult thing. We are looking  
2 for any sorts of advice as to how you would capture and to  
3 what extent you would use or what process you would use to  
4 capture it.

5 Does that help you a little bit, Cathy?

6 MS. ALLEN: Yes, it does, but it strikes me  
7 that you already appear to have a mechanism to do that  
8 without putting language in the rules. You learn about  
9 misadministrations or events, and you publicize this  
10 information widely. I would think that the regulatory  
11 community and the licensees are made aware of root causes  
12 for accidents and things that have happened.

13 And I know that when we have meetings with our  
14 licensees, we tell them war stories or give them advice  
15 about things that might be a problem. And I think there  
16 are organizations that meet, health physics societies,  
17 medical communities, that meet, and talk about problems  
18 and ways that they've resolved them.

19 I guess I'm not convinced of the need to have  
20 language in the rule that says, "And if we find something  
21 that would be helpful, we'll tell you."

22 FACILITATOR CAMERON: Does that suggest that  
23 -- there should be status quo without the precursor. Is  
24 that right?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MS. ALLEN: Right. I guess I'd like to see a  
2 1.5 with no mention of precursors.

3 DR. COOL: Just to finish off that particular  
4 discussion, I think what the Commission really wanted the  
5 staff to at least explore -- and that's certainly a view  
6 which maybe we should take back to them. I think what  
7 they wanted us to explore was: Is there a way to capture  
8 a set of events before they actually got to  
9 misadministrations, which is where they're being captured  
10 now and being reported now?

11 FACILITATOR CAMERON: Okay. Steve? And I  
12 hope everybody understands the distinction there. I think  
13 we all do. Steve?

14 MR. COLLINS: Steve Collins from Illinois.  
15 To follow up a little bit further with  
16 agreement with Cathy, I see this as two different things.  
17 And I would like to see part of the reportable stuff go  
18 away, as I stated earlier, for the medical policy  
19 statement, where that's not really messing into the  
20 practice of medicine and the physician-patient  
21 relationship.

22 But what I would like to see is, as health  
23 physicists in radiation safety issues, going back to  
24 something that's reportable only to the radiation  
25 regulatory agency. And that would be basically any time

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 you have a screw-up and you're not following your  
2 procedure properly and something goes wrong, you report to  
3 us and let us evaluate that from a health physics point of  
4 view and not base this strictly on: Did the patient get  
5 too much dose or something?

6           We've got two different things going here that  
7 are all mixed up together, and that causes part of the  
8 problem.

9           FACILITATOR CAMERON: Perhaps they have two  
10 different objectives or both of them have the same  
11 objective. I think that you flagged a point for us for  
12 the workshops. In other words, the value is not only to  
13 get the agreement state perspective, but this is sort of  
14 like playing off Broadway in a sense for us, a learning  
15 experience to go in and to make sure we have the best  
16 workshops.

17           The medical policy statement, as you pointed  
18 out, keeps coming up. And it came up in the training and  
19 experience area before. Maybe what we should do is when  
20 we present some of these alternatives later on, we should  
21 point out to people what the implications are of a revised  
22 medical policy statement.

23           At any rate, Aubrey?

24           MR. GODWIN: Whenever you present these, I'd  
25 suggest you have a package that slides abnormal occurrence

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 criteria because I'm not sure everybody's going to know  
2 that in the community. I think that would be good to have  
3 out to everybody.

4           Basically I'm not too interested in getting a  
5 lot of misadministration reports unless there's some way  
6 that it's exceeding like five rem to the individual or I  
7 certainly don't want to get all of these reports where  
8 they overdose somebody for one treatment and they  
9 corrected it over the next two or three treatments. I  
10 just don't see us in that business. That's a medical  
11 decision.

12           Now, if a doctor believes that there's a  
13 misadministration such that it went outside something,  
14 then I'd be happy to accept that. But anything less than  
15 five rem where there's exposure, I'm just not real sure  
16 I'd be very interested in it, which would take out just  
17 about everything in diagnostic and a good chunk of your  
18 therapeutic, particularly where they can correct it out  
19 over total dose considerations.

20           I'm not sure where precursor -- I still want  
21 to understand that.

22           FACILITATOR CAMERON: Okay. Thanks, Aubrey.  
23           Stuart?

24           MR. LEVIN: Levin from Pennsylvania.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           The precursor sounds to me like what I would  
2 call a near miss of a noncompliance of a regulation, which  
3 means you're in compliance but you almost were out of  
4 compliance. And we get occasional calls from our  
5 regulated community when something like that happens, but  
6 they know we're not going to run out and yell and scream  
7 at them and give them civil penalties and all that good  
8 stuff like other organizations might.

9           Near misses probably should be recorded. And  
10 somehow information disseminated so somebody else doesn't  
11 make the mistake, but you shouldn't be punished for doing  
12 a good deed.

13           FACILITATOR CAMERON: I don't know if this is  
14 reflected in our options, but the point that Steve made  
15 earlier about there may be a reason for knowing about this  
16 from another standpoint other than enforcement, I mean,  
17 delinking some of this from compliance might be very  
18 important.

19           How about patient notification? Roland?

20           MR. FLETCHER: Well, I guess it can be said  
21 sometimes bad memories outweigh enlightened regulatory  
22 changes. The problem, you know, I substitute in Maryland,  
23 where I see licensee to notify. And following looking at  
24 all options, I'm not sure the one that I fell into is even  
25 up there. And that is licensee would always notify

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 Maryland, the referring physician, and ensure that the  
2 patient is notified, not licensee notifies the patient.

3           And the reason that I even bring that up as a  
4 potential option is the fact that we have run into a  
5 situation where we've followed that very procedure.  
6 Licensee notified us. We ensured or at least got verbal  
7 assurance that the licensee notified the referring  
8 physician and verbal assurance that the patients were  
9 notified where that was possible.

10           But years later we were called to question for  
11 that very action. And no one could verify that the  
12 patient was actually ever notified. And it's a little --  
13 you know, I'm a little uneasy with not having that  
14 complete closure.

15           FACILITATOR CAMERON: Okay. Thanks, Roland.  
16 That additional option will be captured.

17           Any other comments up here before we go to the  
18 audience about threshold or patient notification? Don, do  
19 you have a --

20           DR. COOL: Roland has brought up an  
21 interesting point. And so I want to toss it out as a  
22 question to the states just because there may well be some  
23 differences between federal law and state law.

24           One of the things that our General Counsel's  
25 Office is looking into for us right now is whether or not

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 there are, in fact, other federal statutes which, in  
2 essence, would dictate that there be some mechanism for  
3 the individual to know what the federal government knows.

4 This might become particularly important if  
5 you've reached the point where a report was going to be  
6 made to Congress that the individual knows what kind of  
7 information is being circulated around, being provided to  
8 Congress and otherwise.

9 My question to the states is whether there are  
10 similar sorts of things that you may be aware of within  
11 state statutes with regards to openness of information or  
12 notification of information which is contained in your  
13 system of records.

14 FACILITATOR CAMERON: I might ask Steve. The  
15 way that New York does this is different, and there are  
16 benefits to that.

17 MR. GAVITT: In New York, we have laws that  
18 protect patient privacy. And when NRC requests reports  
19 from us regarding misadministrations, we give the basic  
20 information. We do not identify facilities or obviously  
21 the patients.

22 FACILITATOR CAMERON: Okay. That's what I'm  
23 thinking. Thank you.

24 David?

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 MR. SNELLINGS: Yes. I want to go back to  
2 this threshold and reportability and such, --

3 FACILITATOR CAMERON: Okay. Good.

4 MR. SNELLINGS: -- if you don't mind.

5 FACILITATOR CAMERON: No. That's fine.

6 MR. SNELLINGS: I kind of agree with Aubrey  
7 that I don't think I want to know everything that happens,  
8 you know, all of these small things, but I think it's very  
9 important that the management of the facility know the  
10 goings-on. And this may be something that their radiation  
11 safety committee or the oversight committee should get  
12 involved with to fix the problem.

13 To me, you know, as you have these recurring  
14 events, -- and they could be precursors -- as you have  
15 these things, that is something that the management of the  
16 facility should definitely get involved in and fix because  
17 they can lead to bigger things.

18 I kind of go along with Aubrey that there  
19 should be some level of notification of the regulatory  
20 agency, as opposed to every small thing. We could then if  
21 the management -- and it's reported internally within that  
22 facility, we could then look at it during our regulatory  
23 inspection.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1           This kind of comes as a model from a former  
2 life. You know, nuclear power is very similar to doing  
3 this kind of thing.

4           FACILITATOR CAMERON: Thank you, David.  
5 That's instructive.

6           Aaron?

7           MR. PADGETT: I would just like to support  
8 that. Ten years ago at INPO, we were stressing very, very  
9 strongly the use of precursor events by the management in  
10 the facility. And I think the utilities have used those  
11 very well to cut dose and do other things like this.

12           I have some problem with them trying to  
13 capture them and report them up to the regulatory agency  
14 and this kind of thing. But the use of precursors by the  
15 management in the facility is an invaluable tool in  
16 improving your program.

17           MR. SNELLINGS: Most assuredly. Yes, it is.

18           FACILITATOR CAMERON: And that might be -- we  
19 were talking before about just setting functions or  
20 objectives for radiation safety committees. I suppose you  
21 could have some sort of a statement like that.

22           Is it too difficult to -- are there too many  
23 parameters connected to these options to get a feel for  
24 where all of you stand on this at this point? Probably  
25 need more information before you could say, "Well, we

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 definitely like Option 2" or "We definitely don't like  
2 Option 5," something like that? Okay. Cathy?

3 MS. HANEY: How about from the standpoint of  
4 let's say we do have to do something with precursor events  
5 because that's in the SRM that we're dealing with right  
6 now. Is there a feeling about whether it should be a  
7 voluntary report or a requirement for a report to us, the  
8 voluntary versus regulatory requirement, or, again, is it  
9 too early to ask that question or have I not --

10 FACILITATOR CAMERON: Or do we say that it's  
11 fine if the facility knows about the precursor events?  
12 Aaron, do you have any feel on that?

13 MR. PADGETT: Again, this is just one person's  
14 thoughts, but my thoughts are the facility ought to  
15 identify them. They ought to show that yes, we have  
16 looked at them, yes, we have used them when you're there  
17 on inspections. But as far as reporting them up the line,  
18 I really don't see a great deal of value in that.

19 There is some if there was a mechanism to then  
20 share them within the industry. I don't see that  
21 mechanism. And so I really right now don't see a lot of  
22 value in that.

23 MR. SNELLINGS: I think when you start sending  
24 them up the line, you're going to inhibit the reporting of  
25 them. I think that these precursors are small events that

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 could lead to something bigger. And you want them  
2 reported. Definitely management wants them reported so  
3 that they can then look at the big picture.

4 I don't see any reason to report them to you.  
5 I really don't.

6 MS. HANEY: Yes.

7 FACILITATOR CAMERON: Okay. Ed, one more  
8 comment on that before we go to the public. Ed?

9 MR. BAILEY: Yes. I can think of one example.  
10 And I haven't been close enough to it. So people can fill  
11 in. There was a time in nuclear medicine apparently one  
12 of the gallium and something else had very similar-colored  
13 labels on them. And there were several episodal events  
14 about where somebody grabbed something and thought they  
15 had something else just by the color.

16 Those kind of things I think got -- I don't  
17 know. Have they been corrected? Somebody that knows  
18 ought to --

19 DR. MARCUS: Yes.

20 FACILITATOR CAMERON: Okay. How about Bob  
21 Hallosay? All right.

22 MR. HALLOSAY: Hallosay from Massachusetts.

23 I wanted to address Don Cool's last question  
24 since he came back in the room. In our particular state,  
25 the Health Care Quality Group does address patient

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1 notification and is sort of the group that follows HCFA  
2 requirements. So you may want to look in the HCFA area.

3 FACILITATOR CAMERON: Okay. HCFA being Health  
4 Care?

5 MR. HALLOSAY: Health Care Financing  
6 Administration.

7 FACILITATOR CAMERON: And they have  
8 requirements that deal with patient notification.

9 MR. HALLOSAY: At least in our state level,  
10 they do that.

11 FACILITATOR CAMERON: Okay. I mean, that's  
12 another option. Okay. Good. Thanks, Bob.

13 Going to the medical community, any comments  
14 on either threshold, patient notification? Could one of  
15 you give us sort of a -- yes?

16 DR. WEXLER: This regards this precursor  
17 business. I'm Marilyn Wexler, a medical physicist here in  
18 Los Angeles.

19 Most of you regulators don't work in hospitals  
20 and aren't real familiar with a lot of these programs that  
21 are ongoing that the Joint Commission of Hospital  
22 Accreditation forces these hospitals into.

23 We have millions of ways of reporting events.  
24 We have something called CQI, AQU. I mean, we have 30

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 different programs at work for us to document problem  
2 areas and ongoing audits of potential problem areas.

3 I would really urge the NRC to really look to  
4 the Joint Commission and see the programs they have in  
5 place now so that you don't duplicate what's going on. To  
6 think that a hospital is not undertaking a precursor issue  
7 area right now is crazy. They're looking at the stuff all  
8 the time. They're constantly being looked at. There are  
9 reams of paperwork being developed on a daily basis for  
10 this kind of stuff.

11 So I really hate to see the NRC spend my  
12 money, your time, and additional time on hospitals  
13 duplicating what's already being done. That's on  
14 precursors.

15 Number two, patient notification. This is an  
16 old pet peeve of mine. It's not even a pet peeve. I do a  
17 lot of medical malpractice reviews for radiation oncology  
18 problems. My husband is a radiation oncologist. There is  
19 no way that -- I work in radiation oncology. There is no  
20 way that I would ever expect to ask a physician to notify  
21 a patient by law or by NRC regulations of some kind of  
22 event that happened to that patient.

23 In surgery, the doctor is not required to  
24 notify the patient that he took out the wrong kidney even.  
25 That's called standards of practice, and it's also called

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 tort law. They take care of those issues. They're not  
2 being dictated by some regulatory agency at the state  
3 level or the federal level to notify a patient of  
4 anything.

5 I mean, I don't see where the NRC gets off  
6 thinking that they can force a physician to notify a  
7 patient of any kind of issues.

8 FACILITATOR CAMERON: That's a definite  
9 opinion. That's good.

10 (Laughter.)

11 FACILITATOR CAMERON: And I think you've  
12 raised an important point for us that often when we get to  
13 these workshops, what we want to know is: Is there  
14 something more that we need to know before we go ahead and  
15 regulate?

16 The need to know in this case would be the  
17 existing structure and system within the medical  
18 community, within the hospital for reporting events and  
19 precursors. I mean, before we make any decisions, we may,  
20 as you suggested, need to know that.

21 Carol?

22 DR. MARCUS: I think it's amusing that in one  
23 of NRC's recent regulatory guides, breast-feeding  
24 regulation, it says that you are forced to tell a  
25 breast-feeding mother what would happen to her baby if she

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 didn't stop breast-feeding. And you have to do this in  
2 writing. And if the answer is that there would be no  
3 effect on the baby at all, you have to do that in writing,  
4 too.

5 I mean, this is an example of the NRC being  
6 medically completely inappropriate and off the wall. I  
7 find, even in a county hospital, that the JCAHO  
8 requirements are huge for quality assurance. And  
9 sometimes a mistake here and there is not deemed a very  
10 important thing that issues of general quality in  
11 improvement of 9,999 patients and maybe one  
12 misadministration, it's much more important to improve the  
13 quality of those 9,999 patients.

14 So you again have a very narrow view of what  
15 quality really means. And I think that the medical  
16 institutions who have a broader view are much more  
17 appropriate and that I believe that the NRC should get  
18 completely out of this notification of patients routine.  
19 You have to notify patients because you'll get killed in  
20 court or your risk management people will chop you up if  
21 you try to hide things that have gone on.

22 As far as the threshold reports to the NRC are  
23 concerned, NRC only needs to know certain kinds of things.  
24 Ed mentioned the label colors as a problem. There was  
25 also a situation where Maryland Crouts technetium

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 generators were sitting outside of the airport in St.  
2 Louis and the columns froze and cracked. And then there  
3 was some moly leakage and stuff when people tried to aleut  
4 it.

5           To alert people that that batch has a problem  
6 because of that, this is what I consider to be a service  
7 to the public that NRC or an agreement state group can do.  
8 Everyone now has Web sites through the internet and fax  
9 machines. These facts tend to get known very, very  
10 quickly, though.

11           The first time a high-dose brachytherapy  
12 source broke off inside a patient, the NRC made a  
13 tremendous propaganda event out of that, but, believe me,  
14 the entire medical community communicated very quickly.  
15 Everybody who had those devices understood: number one,  
16 they can break; number two, that if the device reads that  
17 the source has been successfully retracted, don't believe  
18 it because the way it works is it goes by length, not by  
19 radiation detection, which is what happened in Indiana,  
20 Pennsylvania.

21           So I don't see that any real good is coming  
22 out of these reportable events to the NRC. I have seen  
23 embarrassing situations where the patient suddenly finds  
24 himself on the evening news, such as the situation that  
25 happened in Tripler, when a nurse breast-fed her baby

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 because she didn't tell her doctor she was breast-feeding.  
2 And she had some I-131 on board.

3           It was in the news. It was televised that  
4 night by the NRC. And this poor lady is in Honolulu. She  
5 must feel pretty bad. But to have it all over the  
6 television, where everybody knows who it has to be, I  
7 think is very bad form and as an example of how not to  
8 behave.

9           So I would limit the NRC to certain types of  
10 physics events or things that everyone ought to know about  
11 because it could help. And propaganda maybe is not the  
12 function of the NRC.

13           FACILITATOR CAMERON: Okay. Thank you, Carol.  
14 I think we would probably agree with that, --

15           (Laughter.)

16           FACILITATOR CAMERON: -- although we often  
17 don't recognize it when we see it or do it, I guess.

18           I think that we're at an end to this  
19 substantive session at this point. I just want to thank  
20 -- we're not at the end.

21           DR. WEXLER: Again, Marilyn Wexler from Los  
22 Angeles.

23           Ed Bailey at lunch asked me why I was so quiet  
24 because anybody who knows me knows I'm not quiet at these  
25 kinds of meetings. But just as a comment on the general

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 format of these kinds of meetings, this is my first visit  
2 to an NRC open meeting like this. I'm here as a  
3 representative from AAPM because I'm sitting on their  
4 committee to review the Part 35 revision.

5           And I'd like to say that one reason I have  
6 been quiet is because I was notified of this through the  
7 internet, not directly but somewhat. And I did not  
8 receive an agenda for this meeting. And I found myself  
9 ill-prepared really to comment on what we were going  
10 through because I wasn't aware of what exactly we were  
11 going to cover.

12           I also am aware of the fact that when people  
13 such as yourselves from the NRC, who have spent a lot of  
14 time trying to develop these proposed changes in Part 35,  
15 I know from my personal experience that at this point in  
16 the game I wouldn't blame you if you were somewhat  
17 resistant to taking suggestions from the audience,  
18 unconsciously, subconsciously, or even consciously.

19           I know that individuals who have spent 60, 80,  
20 or 100 hours on trying to get some kind of program  
21 together or changes in a policy are really a little bit  
22 resistant to hearing negative comments about that at this  
23 point.

24           I think it would have been a lot more  
25 productive if we professional organizations would have

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1 been involved and medical organizations in a lot earlier  
2 stage of the game, not to say that we're not going to  
3 certainly be involved in it now, but I just know from my  
4 experience.

5 I've sat on a million committees. I've  
6 developed a million policies and procedures and programs.  
7 It's a lot harder to get comments through after the fact  
8 than during the very early developmental stages.

9 FACILITATOR CAMERON: Thanks for that,  
10 Marilyn. Hopefully we are trying to do that with the two  
11 workshops and all of the material that are on the  
12 internet. In fact, the associations have been heavily  
13 involved in that. This was sort of a strange meeting from  
14 that respect because it was part of the agreement states  
15 meeting.

16 Thank you for that. I wanted to thank you and  
17 all of the other people from the medical community who  
18 came and thank Carol Marcus for coordinating that.

19 Don Flater?

20 MR. FLATER: Again, I need to bring up  
21 something to be concerned about. We've been talking about  
22 hospitals. What about private practice? These thresholds  
23 of reportable events, nobody requires them to report  
24 anything to anybody.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701



1           And so don't just think that we have to deal  
2 with hospitals. We've got to deal with private practice.  
3 We've got to deal with the issue of clinics and some of  
4 those kinds of things. And with this outpatient care  
5 thing going on, the use of those kinds of institutions may  
6 well increase tremendously. So don't forget there's  
7 somebody besides hospitals out there.

8           FACILITATOR CAMERON: Okay. Cathy, you've got  
9 that. Thanks, Don. And I know that this part of the  
10 meeting is adjourned, and I know that you're going to go  
11 into a business meeting of sorts.

12                   (Laughter.)

13           FACILITATOR CAMERON: I asked Bob if I could  
14 just say a few words from the facilitation standpoint  
15 before you got into that. And I think you may want to  
16 take a break.

17                   I just wanted to say it was a real pleasure  
18 working with all of you again. I apologize that we did  
19 have a little problem running on schedule. And I probably  
20 could have been harder with some of the presenters. I  
21 think we got some good information out. Also I think  
22 suggestions for future agendas, maybe we try to do less  
23 and not feel so harried and perhaps have the time for some  
24 more quality discussions.

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701

1                   But the last thing I want to say is I think  
2 the taxpayers from your states should be really proud  
3 because you're a dedicated group to sit through all of the  
4 presentations. You were there. You were interested. You  
5 were commenting. I was really impressed by all of that.  
6 And I just wanted to leave you with that.

7                   Thanks.

8                   (Whereupon, the foregoing matter was concluded  
9 at 3:00 p.m.)

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

**NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS  
1323 RHODE ISLAND AVE., N.W.  
WASHINGTON, D.C. 20005-3701