

Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Committee on the
Medical Uses of Isotopes

Docket Number: (n/a)

Location: (teleconference)

Date: Tuesday, March 5, 2013

Work Order No.: NRC-4041

Pages 1-112

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

1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

3 + + + + +

4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 TELECONFERENCE

7 + + + + +

8 TUESDAY, MARCH 5th, 2013

9 + + + + +

10 The meeting was convened via teleconference
11 at 2:00 p.m., Leon S. Malmud, M.D., ACMUI Chairman,
12 presiding.

13 MEMBERS PRESENT:

14 LEON S. MALMUD, M.D., Chairman

15 BRUCE THOMADSEN, Ph.D., Vice Chairman

16 DARICE G. BAILEY, Agreement State Representative

17 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

18 SUSAN LANGHORST, Ph.D., Radiation Safety Officer

19 STEVEN MATTMULLER, Nuclear Pharmacist

20 CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine
21 Physician

22 ORHAN SULEIMAN, Ph.D., FDA Representative

23 WILLIAM VAN DECKER, M.D., Nuclear Cardiologist

24 LAURA WEIL, Patients' Rights Advocate

25 JAMES WELSH, M.D., Radiation Oncologist

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

ACMUI MEMBERS NOT PRESENT:

JOHN SUH, M.D., Radiation Oncologist

NRC HEADQUARTERS STAFF PRESENT:

PAMELA HENDERSON, Deputy Director, Division of
Materials Safety and State Agreements

CHRIS EINBERG, Designated Federal Officer

ASHLEY COCKERHAM, Alternate Designate Federal
Officer, ACMUI Coordinator

SOPHIE HOLIDAY, Alternate ACMUI Coordinator

NEELAM BHALLA, FSME/DILR/RPMB

SUSAN CHIDAKEL, OGC/GCLR/RMR

SAID DAIBES, Ph.D., FSME/DMSSA/RMSB

JAMES DANNA, FSME/DILR/RB-B

TREMAINE DONNELL, OIS/IRSD/ISB/ICT

SANDRA GABRIEL, Ph.D., FSME/DMSSA/RMSB

DONNA-BETH HOWE, Ph.D., FSME/DMSSA/RMSB

ED LOHR, FSME/DILR/RPMB

DEBBIE PISKURA, FSME/DMSSA/RMSB

GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/RMSB

SANDRA TALLEY, FSME/DWMEP

RONALD ZELAC, Ph.D., FSME/DMSSA/RMSB

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

NRC REGIONAL STAFF PRESENT:

MARYANN ABOGUNDE, R-I

HECTOR BERMUDEZ, R-II

COLLEEN CASEY, R-III

JACKIE COOK, R-IV

SARA FORSTER, R-III

MICHELLE HAMMOND, R-IV

PENNY LANZISERA, R-I

DENNIS O'DOWD, R-III

BRYAN PARKER, R-III

PATTY PELKE, R-III

MICHELLE SIMMONS, R-IV

JACK WHITTEN, R-IV

PUBLIC PARTICIPANTS PRESENT:

SUE BUNNING, Society of Nuclear Medicine and
Molecular Imaging

WILLIAM DAVIDSON, University of Pennsylvania

DAWN EDGERTON, Council for Certification in
Cardiovascular Imaging

LYNNE FAIROBENT, AAPM

THOMAS HUSTON, Department of Veterans Affairs,
National Health Physics Program

KAREN LANGLEY, University of Utah

RALPH LIETO, St. Joseph Mercy Hospital

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 ANDREW McKINLEY, American Society of Nuclear
2 Cardiology

3 RICHARD PEARLSTEEN, New Jersey Department of
4 Environmental Protection

5 MIKE PETERS, American College of Radiology

6 JOE RODGERS, Theragenics Corporation

7 GLORIA ROMANELLI, American College of
8 Radiology

9 KAREN SHEEHAN, Fox Chase Cancer Center

10 MICHAEL SHEETZ, University of Pittsburgh

11 MICHAEL STEPHENS, Florida Bureau of Radiation
12 Control

13 CINDY TOMLINSON, American Society for Radiation
14 Oncology
15

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

CONTENTS

1		
2	ACMUII Rulemaking Subcommittee Report	11
3	Item 1-A, Historical review of permanent implant	
4	brachytherapy misadministration/medical event ...	28
5	Item 1-C, Supplementary Information Section IV-D for	
6	Permanent Implant Brachytherapy,	40
7	Item 1-D, Compatibility Category for Agreement	
8	States	51
9	1-E, Literature Citation	53
10	Item 2-B, AU Work Experience on Elution of	
11	Generators	54
12	Item 2-C, Amending Preceptor Attestation	
13	Requirements	66
14	Item 2-D, Parenteral Administrations	84
15		

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

P R O C E E D I N G S

2:03:02 p.m.

MR. EINBERG: Okay, we'll get started. As the Designated Federal Officer for this meeting I am pleased to welcome you to this public meeting of the Advisory Committee on Medical Uses of Isotopes.

Before I continue, is the court reporter on the line?

COURT REPORTER: Yes, I am. Could you please tell me who is speaking?

MR. EINBERG: This is Chris Einberg. I'll start once again.

As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My name is Chris Einberg. I am the Chief of the Radioactive Material Safety Branch, and I've been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the alternate Designated Federal Officer is Ashley Cockerham, who is the coordinator for the Committee.

This is an announced meeting of the Committee. It is being held in accordance with the rules

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and regulations of the Federal Advisory Committee Act
2 and the Nuclear Regulatory Commission. The meeting was
3 announced in the February 1st, 2013 edition of the Federal
4 Register, Volume 78, page 7465.

5 The function of the Committee is to advise
6 the staff on issues and questions that arise in the
7 medical use of byproduct materials. The Committee
8 provides counsel to the staff, but does not determine
9 or direct the actual decisions of the staff or the
10 Commission. The NRC solicits the views of the Committee
11 and values their opinions.

12 I'd request that whenever possible we try
13 to reach a consensus on the procedures that we will
14 discuss today, but I also recognize there may be a
15 minority or dissenting opinion. If you have such opinions
16 please allow them to be read into the record.

17 At this point I would like to perform a roll
18 call of the ACMUI Members participating today. Dr. Leon
19 S. Malmud, the ACMUI Chairman.

20 CHAIRMAN MALMUD: Here.

21 MR. EINBERG: Dr. Bruce Thomadsen, Vice
22 Chairman, Therapy Medical Physicist.

23 VICE CHAIRMAN THOMADSEN: Here.

24 MR. EINBERG: Ms. Darice Bailey, State
25 Government Representative.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER BAILEY: Here.

2 MR. EINBERG: Dr. Mickey Guiberteau,
3 Diagnostic Radiologist.

4 MEMBER GUIBERTEAU: Here.

5 MR. EINBERG: Dr. Sue Langhorst, Radiation
6 Safety Officer.

7 MEMBER LANGHORST: Here.

8 MR. EINBERG: Mr. Steve Mattmuller, Nuclear
9 Pharmacist.

10 MEMBER MATTMULLER: Here.

11 MR. EINBERG: Dr. Christopher Palestro,
12 Nuclear Medicine Physician.

13 MEMBER PALESTRO: Here.

14 MR. EINBERG: Dr. John Suh, Radiation
15 Oncologist.

16 Dr. Orhan Suleiman, FDA Representative.

17 MEMBER SULEIMAN: Here.

18 MR. EINBERG: Dr. William Van Decker,
19 Nuclear Cardiologist.

20 Laura Weil, Patients' Rights Advocate.

21 MEMBER WEIL: Here.

22 MR. EINBERG: Dr. James Welsh, Radiation
23 Oncologist.

24 MEMBER WELSH: Here.

25 MR. EINBERG: Dr. Pat Zanzonico, Nuclear

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Medicine Physicist.

2 MEMBER ZANZONICO: Yes.

3 MR. EINBERG: Okay, we have a quorum. We have
4 at least seven members.

5 I now ask the NRC Staff Members who are
6 present today to identify themselves. We'll start with
7 the people in the room here.

8 MS. CHIDAKEL: Susan Chidakel, Senior
9 Attorney, Office of General Counsel.

10 MS. HENDERSON: Pam Henderson, FSME.

11 MS. HOLIDAY: Sophie Holiday, FSME.

12 DR. DAIBES: Said Daibes, FSME.

13 MS. RIVERA-CAPELLA: Gretchen
14 Rivera-Capella with FSME.

15 MS. PISKURA: Debbie Piskura, FSME.

16 MS. BHALLA: Neelam Bhalla, FSME.

17 MR. LOHR: Ed Lohr, FSME.

18 MS. TALLEY: Sandra Talley, FSME.

19 MR. EINBERG: Okay. Now I'd like to go to
20 Region I.

21 MS. LANZISERA: We have Penny Lanzisera and
22 MaryAnn Abogunde.

23 MR. EINBERG: Thank you.

24 MR. BERMUDEZ: And Hector Bermudez.

25 MR. EINBERG: Okay, thank you. Region III?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MS. PELKE: Patty Pelke.

2 MS. CASEY: Colleen Casey.

3 MS. FORSTER: Sara Forster.

4 MR. PARKER: Bryan Parker.

5 MR. O'DOWD: Dennis O'Dowd.

6 MR. EINBERG: Okay, thank you. And Region

7 IV.

8 MR. WHITTEN: Jack Whitten.

9 MS. HAMMOND: Michelle Hammond.

10 MS. SIMMONS: Michelle Simmons.

11 MR. EINBERG: Okay. And now anybody else from
12 Headquarters who is calling in remotely?

13 DR. HOWE: Donna-Beth Howe.

14 DR. GABRIEL: Sandy Gabriel.

15 DR. ZELAC: Ron Zelac.

16 MS. COCKERHAM: Ashley Cockerham.

17 MR. EINBERG: Okay. And we also have Jim
18 Danna on the phone. We have the bridge line available
19 and that phone number is 888-864-0940. The pass code
20 to access the bridge line is 35793#.

21 I now ask the members of the public who are
22 present to identify themselves.

23 MS. FAIROBENT: Lynne Fairobent, AAPM.

24 MR. EINBERG: Okay.

25 MS. TOMLINSON: Cindy Tomlinson, ASTRO.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MS. BUNNING: Sue Bunning, SNMMI.

2 MR. HUSTON: Tom Huston, Department of
3 Veterans Affairs.

4 MS. ROMANELLI: Gloria Romanelli, ACR.

5 MR. PETERS: Mike Peters, American College
6 of Radiology.

7 MR. STEPHENS: Mike Stephens, Florida.

8 MS. LANGLEY: Karen Langley, University of
9 Utah.

10 MR. MCKINLEY: Andrew McKinley with ASNC.

11 MS. EDGERTON: Dawn Edgerton, CBNC/CCCVI.

12 MR. EINBERG: Okay.

13 MR. SHEETZ: Mike Sheetz, University of
14 Pittsburgh.

15 MR. RODGERS: Joe Rodgers, Theragenics
16 Corporation.

17 MR. EINBERG: Okay, we're going to proceed
18 then.

19 This is a Category I public meeting. This
20 is an open public observatory meeting that is
21 non-participatory. Members of the public may listen to
22 the meeting. The draft proposed expanded Part 35 rule
23 is considered pre-decisional and has not been
24 transmitted to the NRC Commission for a vote. The rule
25 is anticipated to be sent to the Commission in the later

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 summer of 2013.

2 After Commission approval, the rule will
3 be published in the Federal Register and members of the
4 public will be given a 90-day comment period pending
5 Commission approval versus the typical 75-day comment
6 period.

7 While this meeting is a meeting of the
8 ACMUI, NRC Staff is available to answer questions from
9 the ACMUI members.

10 At this point, I would like to turn the
11 meeting over to Dr. Malmud.

12 CHAIRMAN MALMUD: Thank you. At this point,
13 as Chairman I will turn the Committee over to the
14 Committee Chairman, the Subcommittee Chairman, Dr.
15 Zanzonico, who has an extensive report for us. Dr.
16 Zanzonico.

17 MEMBER ZANZONICO: Yes. Thank you, Dr.
18 Malmud. Hello, everyone.

19 I'm Pat Zanzonico from Memorial
20 Sloane-Kettering Cancer Center in New York City, and
21 I had the pleasure of serving as the chairperson of the
22 ACMUI Subcommittee on the proposed rule.

23 Our report has been made publicly available
24 through the NRC, and presumably members of the public
25 as well as of the NRC and, of course, members of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 ACMUI have had an opportunity to look at it. So, I think
2 I will just summarize some of the major points and then
3 we can move on to a discussion.

4 I should point out that to expedite our
5 review, the review of the Subcommittee, we inserted line
6 numbers into the proposed rule, and many of our comments
7 reference both the page and line numbers, especially
8 with respect to specific comments. And we divided our
9 report into two major sections, general comments which
10 basically deal with major regulatory issues in a general
11 way, significant specific comments, again referenced
12 by line and page numbers, and minor specific comments,
13 really editorial comments likewise referenced by page
14 and line number.

15 And the real key component of our report,
16 of course, are the general comments. And we had seven
17 such areas that we identified in the draft -- in the
18 proposed rule upon which we commented. And I'd also like
19 to thank all my fellow members of the Subcommittee for
20 their time, effort, and due diligence. I mean, everyone
21 really put in a lot of time, and effort, and thought
22 into submitting comments and reviewing the proposed
23 rule. And in advance of this meeting there was a lot
24 of give and take, very collegial, but give and take,
25 nonetheless, among the members of the Subcommittee.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, just to go through the general comments.
2 The first issue, and I think really the most contentious,
3 for lack of a better term, was the proposed definition
4 of a medical event for permanent implant brachytherapy.
5 And the key features of the new proposed definition which
6 was based on the recommendations of a Subcommittee of
7 the ACMUI, and subsequently endorsed by the entire
8 Committee, basically expresses or defines a medical
9 event in permanent implant brachytherapy largely in
10 terms of source strength in the proposed rule rather
11 than in terms of radiation absorbed dose. And I think
12 that's the key distinction.

13 Now, it was pointed out by at least one
14 member of our Subcommittee, and we included a sort of
15 historical review of the -- or the evolution of the ME
16 definition in the regulatory literature. And at least
17 one member of the Subcommittee pointed out that really
18 the proposed rule for an ME for permanent implant
19 brachytherapy is actually not fundamentally different
20 in our opinion from the existing definition. So, in that
21 it allows a definition of an ME in terms of source
22 strength or activity rather than dose, or in addition
23 to dose.

24 So, one suggestion was made that until the
25 proposed rule is finalized and adopted it might be

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 prudent to include activity-based MEs until that rule
2 is adopted, because it is, in fact -- such a definition
3 is, in fact, consistent with the existing regulation,
4 the regulatory language in our opinion.

5 Another issue that was raised by the
6 Subcommittee was concern about the complexity or
7 perceived complexity of the proposed ME definition for
8 permanent implant brachytherapy. And this was
9 specifically related to the provision in which an ME
10 -- one of -- or two of the criteria for an ME in permanent
11 implant brachytherapy was a dose to five contiguous cubic
12 centimeters of normal tissue whether it was within the
13 treatment site or outside of the treatment site. So,
14 additional criteria in the new ME definition would mean
15 that if the dose to such a five cubic centimeter
16 contiguous volume of normal tissue exceeded the
17 prescribed absorbed dose to the target by more than 20
18 percent, that would meet the criteria for a medical
19 event.

20 So, there was some concern that that might
21 be onerously complex in the field for both users and
22 regulators for inspection. So, one suggestion was made
23 that the NRC solicit from stakeholders some feedback
24 on whether the complexity or perceived complexity of
25 the ME definition in that respect might discourage

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 practitioners from using permanent implant
2 brachytherapy, you know, simply to avoid that
3 complexity. Apparently, in supplemental information
4 Section 4D, there's a provision for soliciting such
5 feedback from stakeholders.

6 Another concern with respect to the ME
7 definition was the compatibility category assigned to
8 the proposed ME definition for permanent implant
9 brachytherapy. And the current designation is as
10 Compatibility Category C, which to our understanding
11 allows Agreement States to retain the dose-based
12 criteria for definition of an ME. And it was explained
13 very eloquently in the proposed rule the rationale for
14 moving from a dose-based to an activity-based criteria;
15 the most important consideration being that the
16 dose-based criteria seemed not to be sensitively and
17 specifically capturing clinically significant medical
18 events, and even certain, for lack of a better term,
19 bookkeeping issues which really had little to no clinical
20 impact were being designated or defined as MEs.

21 So, it seemed that if the designation of
22 Compatibility Category C were allowed to stand, that
23 that confusion or lack of sensitivity and specificity
24 for clinically significant ME's would be perpetuated,
25 so our Subcommittee recommended that this new definition

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of MEs for permanent implant brachytherapy be designated
2 as Compatibility Category B.

3 We also, thanks to Dr. Welsh, identified
4 a literature reference, a specific reference in support
5 of the five cubic centimeter of contiguous normal tissue
6 criteria for an ME, and we included that reference which
7 is from a working group. We included that reference in
8 our comments.

9 So, I believe those summarize our major
10 concerns with and comments on the proposed definition
11 for an ME for permanent implant brachytherapy. So, I
12 presume we're going to hold discussion until I've gone
13 through the synopsis of the report. Is that correct,
14 Dr. Malmud?

15 CHAIRMAN MALMUD: That would be the most
16 efficient way to handle it, I believe.

17 MEMBER ZANZONICO: Agreed, agreed.

18 Okay. So, in that case then I'll just move
19 on to the second issue we addressed in our report which
20 was the training and experience requirements for
21 authorized users, medical physicists, radiation safety
22 officers, and nuclear pharmacists. And our Subcommittee,
23 and I think the entire ACMUI is unanimously enthusiastic
24 about eliminating the preceptor statement requirement
25 for Board certified individuals. That was just kind of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 an endorsement of that point that we wanted to emphasize.

2 A second point had to do with the
3 requirement for authorized users on the elution of
4 generators. It appeared that there was -- it's not an
5 additional, an explicit requirement for T&E, for
6 training and experience on elution of generators. And
7 we felt that that training and experience was adequately
8 -- the requirement for that training and experience was
9 adequately covered in the existing training and
10 experience requirements, and that it was unnecessary,
11 and redundant, and so forth to include a separate
12 training and experience requirement on that particular
13 item. As I say, it was felt that the training and
14 experience requirements overall for authorized users
15 implicitly included that particular item; in other
16 words, elution of generators.

17 The other point we had with respect to
18 training and experience requirements had to do with the
19 language that preceptor attestations would use, and we
20 really felt that it was more than a matter of semantics.
21 For example, on page 19 in Section 4B there was language
22 stating that a preceptor should attest that a authorized
23 user, RSO, et cetera, satisfactorily completed the
24 necessary training and experience requirements, and has
25 achieved the level of competency sufficient to function

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 independently in the position for which authorization
2 is sought. And we felt that as worded such an attestation
3 really puts an untenable burden on preceptors in that
4 it requires them to make a subjective judgment as to
5 the professional competency of an individual. And what
6 we felt was actually being sought, and what was more
7 appropriate was somewhat amended language; namely, has
8 satisfactorily fulfilled the training and experience
9 requirements consistent with achieving a level of
10 competency sufficient to function independently in the
11 position for which authorization is sought.

12 And, again, the distinction is subtle, but
13 we think not insignificant between the proposed and this
14 new language in that it eliminates the burden on the
15 preceptor to make a subjective judgment as to
16 professional competency or not. Rather, it simply asks
17 the preceptor to attest that the person seeking
18 authorization had satisfied residency and other
19 requirements of a training program. And we think that's
20 a significant in language. And if you read our report
21 you saw that we -- that that sort of language and the
22 suggested change was made at multiple points throughout
23 the proposed rule and throughout our comments.

24 The final point we had with respect to
25 training and experience requirements was -- had to do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 with certain elements of Section 35.390. And lines 1503
2 to 1508 in that section states that the current
3 regulation include a broad category for parenteral
4 administration of any other radionuclide. This broad
5 category would be removed as any new parenteral
6 administration of radionuclides not listed in this
7 paragraph would be regulated under 35.1000.

8 "This approach would allow the NRC to review
9 each new proposed radionuclide for parenteral
10 administration and determine the appropriate training
11 and experience for its use."

12 And the reservations we have about that is
13 that it appears it would require each new
14 radiopharmaceutical -- that the training and experience
15 requirements for each new radiopharmaceutical that might
16 be introduced. For example, as we recently saw the
17 radium-223 dichloride issue. And our feeling was that
18 an authorized user who has demonstrated acceptable
19 training, and experience, and so forth for any one
20 category of radiopharmaceuticals such as gamma and beta
21 emitters has demonstrated adequate training and
22 experience for all radiopharmaceuticals, that in terms
23 of radiation physics, radiation safety, radiation
24 biology, and clinical applications, all of these
25 radiopharmaceuticals are much more alike than they are

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 different. And it would just seem to be unnecessarily
2 burdensome and so forth to allow the possibility of
3 radiopharmaceutical by radiopharmaceutical review of
4 credential as new radiopharmaceuticals are introduced.
5 And it sounds like, or at least we infer from the language
6 as proposed that that might be the case.

7 So, that concludes our comments on the training and
8 experience provisions of the proposed rule.

9 The next issue is extending grandfathering
10 to certain certified individuals. And this is -- has
11 come to be known as the Ritenour petition. And the ACMUI
12 had previously recommended that all board-certified
13 individuals, individuals certified by Boards
14 recognized, professional Boards recognized by the NRC
15 should be grandfathered, and that should be independent
16 of the date of the recognition of the Board by the NRC.

17 You know, the ACMUI has argued that the most
18 appropriate group of individuals to judge the
19 professional qualifications of a practitioner are that
20 practitioner's professional peers, namely, the Boards.
21 And that certainly we understand the NRC has a regulatory
22 obligation to review Boards themselves and to decide
23 which Boards are or not acceptable. But we felt that
24 an arbitrary date and time was not reasonable, that once
25 a Board has been recognized and regardless of the date

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 of board-certification of an individual, or the date
2 of recognition of that Board by the NRC, that that
3 board-certification should be de facto evidence for the
4 NRC of that individual's qualifications, professional
5 qualifications.

6 There was a second point that was raised
7 by our Subcommittee in terms of certain terminology the
8 NRC has used and is using. And terms such as type of
9 use, modality, and category should be explicitly defined
10 in Section 35.2 definitions so that the regulatory
11 meaning of these three terms, in particular, be
12 understood.

13 And, again, a third point, but it's really
14 related to the first point I made, as well, was the --with
15 respect to the Ritenour petition was the impact of the
16 date of recognition of a certifying Board by the NRC.
17 And just to reiterate, the ACMUI has recommended and
18 still recommends that the date of recognition should
19 not impact individuals seeking to be named as an
20 authorized user or other practitioner. Once the Board
21 has been recognized, the date of its recognition is
22 really irrelevant in our opinion.

23 The next general item we addressed and
24 included in the proposed rule is measuring molybdenum
25 contamination for each elution of a molybdenum

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 technetium generator and reporting a failed breakthrough
2 test; that is, a breakthrough test in which the
3 molybdenum concentration was out of tolerance.

4 And it was pointed out, of course, that
5 currently there are two generator systems in routine
6 use in nuclear medicine; of course, the molybdenum-99,
7 technetium-99 generator system, and the strontium-82,
8 or strontium-89, rubidium-89 generator systems for
9 cardiac studies. And as has been pointed out, there are
10 other generator systems like gallium/germanium
11 generator systems that are on the horizon, so we raised
12 the issue of whether these newer generator systems should
13 be included in the proposed rule, or should it somehow
14 be generalized to include all current and future
15 generator systems.

16 The other issue had to do with the NRC
17 regulation in terms of breakthrough, generator
18 breakthrough as it relates to FDA labeling requirements.
19 And at least one of our Subcommittee members felt very
20 strongly that a better way overall of regulating
21 generator breakthrough testing would be to simply defer
22 to the FDA labeling requirements. The FDA will, of
23 course, promulgate labeling requirements for every
24 generator system as it becomes a marketed product, so
25 if the NRC were to defer to the FDA labeling requirements

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 on this point, then it would automatically take care
2 of the NRC regulation for these newer generators as
3 they're introduced into clinical use without the need
4 for a revision of existing rules, and all of the time,
5 and effort, and review that that entails, as well.

6 The NRC argued in the proposed rule and made
7 a number of arguments as to why it felt that was not
8 an optimum way to go, but without going into it on a
9 point by point basis, in our report we address the NRC's
10 arguments on this point; namely, the NRC's rationale
11 as to why their own regulation rather than FDA labeling
12 requirements would be more appropriate. And our
13 conclusion was that we really -- we meaning the
14 Subcommittee did not find those arguments compelling,
15 and really felt that deferring to the FDA labeling
16 requirements would ultimately be a more effective and
17 more expeditious way of dealing with this issue.

18 And, you know, there was also concern about
19 the reporting requirement itself. In the proposed rule,
20 the NRC is basically requiring that licensees submit
21 to at least two notifications, one to the NRC and one
22 to the vendor or manufacturer within 24 hours of the
23 finding of an out-of-tolerance elution result. And our
24 Subcommittee felt that was really -- that was somewhat
25 excessive, that if the licensee simply reported the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 out-of-tolerance elution results to the vendor, and then
2 required the vendor to report to the NRC, that that would
3 be sufficient. And that's standard practice, so would
4 not introduce any additional regulatory burden on
5 licensees.

6 We also thought it might be useful to
7 increase that reporting requirement interval from four
8 hours to 48 or even 72 hours because there might be
9 instances in which a licensee on a weekend or some such
10 thing as that where they're really short-staffed might
11 encounter such a result, and it would really be much
12 more convenient and less intrusive if there were a
13 somewhat longer reporting time interval introduced.

14 There was also -- in light of the recent
15 experience of the strontium-rubidium generator issue
16 recently as to whether the reporting rule -- the proposed
17 reporting rule is really effective and what additional
18 provisions might or might not be introduced to create
19 a more effective rule that would avoid the use of
20 out-of-tolerance elutions in terms of tear and
21 breakthrough, and thereby avoid these really major
22 disruptions of practice such as we experienced with the
23 rubidium generators. So, some of those points are
24 detailed, as well, in our report.

25 And just as we did in the case of the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 permanent implant brachytherapy issue, we suggested that
2 the NRC solicit comments pursuant to Supplementary
3 Information Section 4D from stakeholders on whether the
4 proposed reporting requirements might discourage
5 licensees from using generators.

6 The next item, the next significant item
7 we addressed as allowing Radiation Safety Officers
8 -- Associate Radiation Safety Officers, ARSOs, to be
9 named on a medical license, and our Subcommittee strongly
10 endorsed that recommendation. We had some specific
11 comments in the specific comment section on that point.

12 The next significant issue was simply the
13 -- had to do with the plain language requirement. That's
14 Section 9. And we felt that as well written and as well
15 organized as the proposed rule was, that it perhaps could
16 be shortened and improved further by eliminating some
17 redundancies and consolidating some related sections,
18 and thereby eliminating some identical or nearly
19 identical verbiage that appears multiple times
20 throughout the draft rule.

21 Perhaps even more importantly, we felt that
22 a more detailed Executive Summary-styled section
23 summarizing maybe in the format of a bullet list the
24 key changes introduced in the proposed rule might be
25 helpful, and that would replace the current very general

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 one-paragraph summary in the proposed rule.

2 We had several other minor general
3 comments. These are detailed in our report. And then
4 beyond that, there were a number, as I said, of what
5 we characterized as significant specific comments, and
6 a number of minor or editorial specific comments. But
7 I think -- I certainly don't think it's useful to go
8 through those, so I think I'll stop at this point and
9 leave it up to Dr. Malmud if he thinks it appropriate
10 to open the report for discussion.

11 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
12 That's rather a thorough review of all the material that
13 we've been reviewing via email. And I'd like to first
14 thank you and the members of the Committee for an enormous
15 amount of work that you've done on behalf of these issues.

16 With that may we, Pat, begin with the first
17 item; if you would just remind us of the first item,
18 we'll take them in order.

19 MEMBER ZANZONICO: Yes.

20 CHAIRMAN MALMUD: By the way, I very much
21 appreciate your having numbered the lines on each of
22 the pages so that we could follow them coherently during
23 this discussion.

24 MEMBER ZANZONICO: I'm glad you found that
25 helpful. I think it would have been intractable

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 otherwise.

2 So, the first item has to do with the
3 proposed definition for medical event in permanent
4 implant brachytherapy.

5 CHAIRMAN MALMUD: Are there comments for Dr.
6 Zanzonico and members of the Committee?

7 MEMBER WELSH: Well, this is Jim Welsh, if
8 I might start.

9 CHAIRMAN MALMUD: Please do, Jim.

10 MEMBER WELSH: I appreciate that this is a
11 very complicated issue, and we've gone through years
12 of discussion, if not lively active debate on this topic,
13 and the complicated nature of this is underscored by
14 the lack of consensus presently even in a tiny
15 Subcommittee. However, I would state that in the opinion
16 of most present and past practitioners of permanent
17 implant brachytherapy, that the Permanent Implant
18 Brachytherapy Subcommittee statement is considered
19 acceptable and appropriate; and, therefore, we would
20 not -- at least I would not advocate any kind of
21 significant changes at this point. And particular
22 reference to the historical background that Dr.
23 Zanzonico has alluded to, I would point out that in that
24 context, activity or dose might have been considered
25 acceptable or appropriate. The --

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

(Buzzer sound.)

MEMBER WELSH: -- is that dose is absolutely not appropriate when we are talking about medical event definition for the target or what we call the treatment site.

Having said that, we would not feel that dose was entirely inappropriate for medical event definition if we are excluding treatment site, but focusing rather on adjacent or internal normal structures, and therein we have encountered some controversy and lack of consensus.

The 5cc volume was considered necessary or at least appropriate to come up with some -- it was considered appropriate to come up with some volume so that we're not just talking about a dose without a specific volume or a volume without a specific dose. The two are interrelated; otherwise, it doesn't make a whole lot of sense, and is impractical.

We understand that the 5cc criteria might not be optimal, and it is probably not ideal for prostate as a specific example, but because we have used all forms of permanent implant brachytherapy together in this categorization in this medical event definition, we had to come up with something, and 5ccs seems to be acceptable for most of them. It would probably never cause much

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 difficulty for prostate. And, in specific, we are talking
2 about the refill dose which the volume to the urethra
3 -- the volume of the urethra within the prostate is often
4 not even 5ccs, so by that criteria we might never have
5 a medical event in prostate permanent implant
6 brachytherapy that has been triggered because of
7 excessive dose to an internal structure; but that for
8 other types of permanent implant brachytherapy, it would
9 be inappropriate to have something smaller than 5ccs.

10 So, we felt that sticking with the original
11 definition that was proposed by the Permanent Implant
12 Brachytherapy Subcommittee that we would have an
13 appropriate and acceptable definition that is not too
14 complex, and would not cause practitioners to avoid
15 pursuing this appropriate form of therapy for their
16 patients.

17 And when compared to the current, and what
18 I think is an inappropriate medical event definition
19 for permanent implant brachytherapy, this new
20 definition, even with the perceived complexity, is going
21 to be in practice far less complicated, and far less
22 likely to cause avoidance of brachytherapy than the
23 present situation.

24 Additionally, if we use post-implant
25 dosimetry as has been recommended but not mandated, it's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 not going to be too difficult to implement from a
2 practical perspective. So, I don't think that we would
3 be causing practitioners to eschew permanent implant
4 brachytherapy with this new proposed medical event
5 definition.

6 Finally, as far as Compatibility C, I, for
7 one, would argue that the states should not be allowed
8 to continue to use the inappropriate medical event
9 definition based on dose to the target or treatment site;
10 and, therefore, Compatibility Category B would be most
11 appropriate. So, those are my comments on your points
12 that were brought up, Dr. Zanzonico.

13 CHAIRMAN MALMUD: Pat, do you have any
14 comments about Dr. Welsh's comments?

15 MEMBER ZANZONICO: Well, in our discussions
16 among the members of the Subcommittee, you know, I was
17 in agreement with the sentiments he expressed. I thought
18 the -- as he said, in attempting to base an ME definition
19 in part on an excessive dose to normal tissue, one has
20 to specify some volume because, as we know with seed
21 implants or with any focal sources you can get an almost
22 arbitrarily high dose to an infinitesimally small volume
23 of tissue or points in the immediate vicinity of a source
24 which has no clinical meaning, so I think it's critical
25 that some meaningful volume -- that that ME definition

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 based on -- or criteria for ME based on normal tissue
2 dose have some volume. And, frankly, I defer to others
3 who are far more knowledgeable about this than I,
4 permanent implant brachytherapy, like Dr. Welsh, like
5 Dr. Thomadsen. But I think if those practitioners in
6 that field feel that it's a practical implementable
7 criterion along with the source strength-based
8 criterion, then I'm all in favor of it. And I certainly
9 agree with Dr. Welsh that it's far better than the current
10 dose-based criteria for a permanent implant
11 brachytherapy ME.

12 The one concern I have is actually on behalf
13 of the regulators, and is that a practically inspect-able
14 criterion for a medical event. So, I would ask either
15 Dr. Welsh, or Dr. Thomadsen, or whomever, if they might
16 comment on that point, the inspect-ability of the
17 excessive dose to 5 cubic centimeters of contiguous
18 normal tissue, is that a practically inspect-able
19 criterion?

20 VICE CHAIRMAN THOMADSEN: This is Bruce
21 Thomadsen. I think it's a fairly easily achieved
22 inspection criteria.

23 CHAIRMAN MALMUD: Other comments from other
24 members of the Committee? Is there agreement among the
25 members of the Subcommittee that this is so? Could we

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 have a voice vote about it on the phone? Are all the
2 members of the Committee in agreement?

3 (Chorus of ayes.)

4 CHAIRMAN MALMUD: Are there any abstentions
5 or nays?

6 MEMBER SULEIMAN: That's for this specific
7 -- this is Orhan Suleiman. That's for this specific part
8 of the report?

9 CHAIRMAN MALMUD: Yes, we're taking them one
10 part at a time, Orhan. Thank you for clarifying that.
11 So, is there agreement on this item among all the members
12 of the Subcommittee? If so, does the Subcommittee wish
13 to make that recommendation to the Committee?

14 MEMBER ZANZONICO: Yes. So, I think just to
15 verbalize, or try to make it as explicit as possible
16 what we're recommending, we are recommending that
17 adoption of the proposed definition of a medical event
18 for permanent implant brachytherapy, that's the first
19 point. And I think it's a multi-part vote we're taking,
20 so that would be the part of the vote.

21 I guess I should ask members of the
22 Subcommittee or the ACMUI overall, do we want to formally
23 recommend to the NRC that they solicit feedback from
24 stakeholders as to whether this definition would or would
25 not discourage use of permanent implant brachytherapy,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 or do we feel that that's not -- that's now a non-issue?

2 MEMBER LANGHORST: Dr. Malmud, this is Sue
3 Langhorst. May I speak?

4 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

5 MEMBER LANGHORST: Thank you. Just one way
6 that it might be easier to go through this is, what are
7 the recommendations that we have in our written report
8 right now, and maybe go through them one by one as far
9 as this section goes. For instance, on Item A at the
10 very last sentence we say, "The ACMUI recommends NRC
11 Staff allow use of total source strength as a substitute
12 for total dose for determining medical events for
13 permanent implant brachytherapy until the Part 35
14 rulemaking is complete."

15 Maybe if we go step by step on this, if the
16 Committee agrees with those recommendations.

17 CHAIRMAN MALMUD: Thank you. That's a
18 constructive suggestion.

19 MEMBER ZANZONICO: Agreed.

20 CHAIRMAN MALMUD: Let's move forward with
21 it.

22 MR. EINBERG: Dr. Malmud, Chris Einberg
23 here. If I may suggest, also, every time the ACMUI has
24 a recommendation, if the NRC could -- if you could
25 provide the opportunity for the NRC staff to either

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 comment on that before you guys vote that would be
2 helpful, as well.

3 CHAIRMAN MALMUD: Thank you. And are there
4 comments from the NRC staff before this item is voted
5 upon?

6 MR. EINBERG: Yes, there is; Ms. Neelam
7 Bhalla.

8 MS. BHALLA: Yes. Good afternoon, Dr. Malmud
9 and the Committee members.

10 CHAIRMAN MALMUD: Good afternoon.

11 MS. BHALLA: With regard to Item 1A, the
12 staff feels that this is not part of the --

13 CHAIRMAN MALMUD: Can you speak up, please?
14 I can't hear you.

15 MS. BHALLA: Okay. The staff feels that Item
16 1A is a historical discussion of the ME rule which has
17 been discussed a lot by the ACMUI to the point that,
18 you know, we had done a revised proposed rule, et cetera.
19 So, at this point, especially the last paragraph where
20 it says, "The ACMUI recommends to allow the source
21 strength to be used," this is part of the ongoing issue
22 with the rule, part of the proposed rule. Therefore,
23 when we are going to be presenting your report to the
24 Commission and also our staff responses, we are going
25 to mention that this 1A is not part of the proposed rule,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 rather than what the issue is.

2 MR. EINBERG: Ms. Bhalla, this is Chris
3 Einberg once again. I think that's a useful comment;
4 however, I believe if the ACMUI would like to make that
5 recommendation, you can state in the rulemaking that
6 this is outside the scope of the rule. This, however,
7 may be useful to the staff as we consider our enforcement
8 policy, so it is a useful comment. So, I would just state
9 that if the ACMUI still would like to make that
10 recommendation, we'll certainly entertain that
11 recommendation.

12 MEMBER ZANZONICO: This is Pat Zanzonico.
13 I think it would be useful to include that recommendation
14 even if it were ultimately determined to be outside the
15 scope of not only the proposed rule but the ACMUI's review
16 of the proposed rule because, if nothing else, it would
17 reinforce the unanimous preference for an activity-based
18 ME criteria as opposed to the existing dose-based
19 criteria. So, I think it would be a useful recommendation
20 to have on the record, nonetheless.

21 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
22 And I think that the members of the Subcommittee and
23 members of the Committee agree with you. Someone said
24 something but they were far away from the speaker and
25 it didn't come through. Can you repeat what you said?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MS. HOLIDAY: Dr. Malmud, this is Sophie.
2 I just wanted to make a quick announcement for all parties
3 that are on the teleconference call.

4 CHAIRMAN MALMUD: Yes?

5 MS. HOLIDAY: For all members of the public
6 and for participants who are on the ACMUI or who are
7 staff members that are participating, if you are not
8 speaking at the time, if you would please mute your phone.
9 If your phone does not have that capability you can press
10 *6 and that will mute it for you.

11 Also, while this has already been happening
12 so far, for members that are speaking please state your
13 name so that we can get on the record for the court
14 reporter.

15 CHAIRMAN MALMUD: Thank you, Sophie.

16 MS. HOLIDAY: Thank you.

17 MEMBER WELSH: This is Dr. Welsh.

18 CHAIRMAN MALMUD: Yes, Dr. Welsh?

19 MEMBER WELSH: I apologize to Dr. Zanzonico.
20 He was asking a specific question, and my name came up,
21 and there was a technical failure, and I missed a minute
22 or two of the conversation. If there was anything that
23 I was specifically asked to address, I'm back here again,
24 but I apologize for being out of touch for the past two
25 minutes.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: Thank you. I'm not aware
2 that you were asked to address anything specifically
3 except with regard to your agreement or disagreement
4 with the rest of the Committee -- Subcommittee's
5 recommendation.

6 MEMBER GUIBERTEAU: Dr. Malmud?

7 CHAIRMAN MALMUD: Yes. Who is this, please?

8 MEMBER GUIBERTEAU: This is Mickey
9 Guiberteau.

10 CHAIRMAN MALMUD: Yes, Dr. Guiberteau.

11 MEMBER GUIBERTEAU: Could I -- I can't find
12 a document that has been sent to me that actually gives
13 the members of the Subcommittee. And I can't remember
14 who they might be, but in this discussion, I was not
15 a member of the Subcommittee. It would be helpful for
16 me to know from the -- in that context which speakers
17 are speaking from inside the Committee; that is, they
18 had the benefit of the discussions, and those who may
19 be, you know -- who may have differences with the
20 opinions of the Subcommittee. So, if we could have that
21 information, I think it would be helpful to me and perhaps
22 to those members of the public and others who are
23 listening to this call.

24 CHAIRMAN MALMUD: Thank you. Would you like
25 that emailed to you, the list of the Subcommittee, as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 opposed to --

2 MEMBER GUIBERTEAU: That would be fine for
3 me, if that's the way we're doing it.

4 CHAIRMAN MALMUD: Find it. Sophie, is it
5 possible to do that now during the conference call?

6 MS. HOLIDAY: Would it more beneficial if
7 I go ahead and announce who those Subcommittee members
8 were on the phone?

9 CHAIRMAN MALMUD: All right. If the
10 interested parties have pencils handy you can write down
11 these names.

12 MS. HOLIDAY: Sure, and it will also be
13 included in the transcript on the record.

14 CHAIRMAN MALMUD: Yes.

15 MS. HOLIDAY: So, the Subcommittee
16 Chairperson was Dr. Pat Zanzonico. Additional members
17 include Dr. Susan Langhorst, Mr. Steve Mattmuller, Ms.
18 Laura Weil, Dr. Bruce Thomadsen, and Dr. James Welsh.

19 MEMBER GUIBERTEAU: Thank you very much.

20 MS. HOLIDAY: You're welcome.

21 CHAIRMAN MALMUD: All right. I believe that
22 we had a statement that there was agreement amongst the
23 members of the Subcommittee with regard to Dr.
24 Zanzonico's recommendation, and it was unanimous. So,
25 we hope that the Minutes will reflect that.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Can we move on to the next item, Dr.
2 Zanzonico?

3 MEMBER ZANZONICO: Yes. So, this -- in terms
4 of an actionable item, that would be Item C in Section
5 1; and that is whether to recommend to the NRC -- this
6 is Pat Zanzonico, by the way. Whether we recommend to
7 the NRC that it solicits feedback from stakeholders on
8 whether the proposed ME definition for permanent implant
9 brachytherapy would discourage licensees from using this
10 form of therapy. The alternative is whether we feel now
11 that that would not be the case. I inferred from some
12 of Dr. Welsh's comments that that was his feeling at
13 the moment. So, to put a point on it, should we offer
14 this recommendation or not to the NRC on soliciting
15 feedback?

16 MS. HOLIDAY: Dr. Zanzonico and Dr. Malmud,
17 this is Sophie, if I could interject real quick. I believe
18 the initial recommendation on the table was for the
19 recommendation that was in 1A, so we wanted just a little
20 bit of clarification. I heard that Dr. Malmud said that
21 the Subcommittee had --

22 (Paper shuffled.)

23 MS. HOLIDAY: I do not believe that
24 recommendation was put before the full Committee.

25 CHAIRMAN MALMUD: You are correct, Sophie.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 The Subcommittee unanimously approved it. We can now
2 put it before the full Committee whose members I believe
3 represent a quorum on this phone, on this teleconference.
4 So, therefore, we will put the same motion before the
5 full Committee. Are any -- all in favor?

6 (Chorus of ayes.)

7 CHAIRMAN MALMUD: Any opposed? Any
8 abstentions?

9 (No response.)

10 CHAIRMAN MALMUD: So, the motion carries
11 unanimously.

12 MS. HOLIDAY: Thank you.

13 CHAIRMAN MALMUD: Thank you, Sophie, for the
14 clarification. Dr. Zanzonico, you're on again.

15 MEMBER ZANZONICO: Okay. So, the point I was
16 addressing was Point C, and whether or not we should
17 make a formal recommendation to solicit input as to the
18 impact of the proposed ME definition. So, again, I was
19 specifically addressing my comments to Dr. Welsh and
20 Dr. Thomadsen and, of course, whoever else would care
21 to offer an opinion on the Subcommittee or Committee.
22 But what is the feeling at this point on that possible
23 recommendation?

24 VICE CHAIRMAN THOMADSEN: This is Bruce
25 Thomadsen, and having been at a stakeholders' meeting

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 on this issue in the past, I think we've heard from
2 stakeholders on their preferences. We could do that.
3 I don't think we'll gain much information that we don't
4 already have.

5 MEMBER WELSH: This is Jim Welsh here. I
6 concur with what Bruce has just said. In my introductory
7 statement, I pointed out that we've been debating and
8 discussing this for several years now, and it's apparent
9 that we're never going to get something that is 100
10 percent perfect. But I believe that what we have
11 currently on the table is as close as we're going to
12 get, and although I have no major objection to additional
13 input from stakeholders and societies, I agree with
14 Bruce, that I doubt very much that we're going to have
15 any major changes or alternatives that are being proposed
16 seriously. And, therefore, my concern is one of
17 efficiency.

18 If this process would in any way slow things
19 down, I would not be in favor of it. If it would be
20 time-neutral I have no objections to it, but I don't
21 personally see what would be gained from it.

22 MEMBER ZANZONICO: Okay. This is Pat
23 Zanzonico. So, my perception then is that we can forego
24 that recommendation unless there's any other comment
25 by members of the Subcommittee or the ACMUI. I would

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 suggest that we just forego that item all together then.

2 MEMBER LANGHORST: Pat, this is Sue
3 Langhorst. May I speak?

4 MEMBER ZANZONICO: Please.

5 MEMBER LANGHORST: Okay. I do not share Jim's
6 opinion that this would -- I think we should keep this
7 recommendation. And if we don't keep this
8 recommendation, I would hope that stakeholders will
9 comment on it in their comments on the proposed rule
10 when it is published. So, I think it's not a bad idea
11 to propose this question be asked of stakeholders, but
12 I am not opposed to it being dropped out of this
13 recommendation.

14 MEMBER ZANZONICO: Dr. Malmud, could we then
15 -- unless there is any further comments, can we then
16 move to a vote? And if we follow the model we did on
17 the previous point, we'll have a vote of the Subcommittee
18 followed by a vote of the whole ACMUI?

19 CHAIRMAN MALMUD: Yes. Are all the members
20 of the -- we'll first poll the Subcommittee members.
21 All in favor?

22 (Chorus of ayes.)

23 MS. BHALLA: Dr. Malmud.

24 CHAIRMAN MALMUD: Yes?

25 MS. BHALLA: Yes, this is Neelam Bhalla from

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 NRC.

2 CHAIRMAN MALMUD: Yes.

3 MS. BHALLA: We here discussed also this
4 question and staff thinks that this question, even if
5 we want to keep it perhaps could be phrased in a
6 different way, and we could ask the licensees if the
7 proposed new definition has the clarity, and if it meets
8 the requirements of the working physicians, because when
9 the SRM was issued on this subject, the Commission was
10 very clear on -- to us, to the Staff that it should be
11 -- it should not impede on the practicing physicians;
12 and, yet, it should protect the interest of the patients.
13 And, therefore, we brought this -- the proposed rule
14 is pretty much based on what the ACMUI's recommendations
15 were. So, we could perhaps ask the question in our
16 proposed rule is it -- is the definition clear enough
17 rather than saying about this, you know, if it's going
18 to discourage licensees from using this therapy option.

19 CHAIRMAN MALMUD: Are you suggesting
20 different wording?

21 MS. BHALLA: Yes.

22 CHAIRMAN MALMUD: Do you have the specific
23 wording that you would like to suggest?

24 MS. BHALLA: We could propose something.
25 Actually, we could say doctors, if you must keep

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 something -- in the Statements of Consideration, if you
2 have seen we do ask in general questions about how this
3 rulemaking is going to impact. We do ask general
4 questions, so either we can just leave this right here
5 and because we have the other questions in general, so
6 we could just leave it there, or for the ME definition
7 we could ask -- the language could be, is this revised
8 definition clear enough or -- I didn't bring the right
9 words, the exact words, but something to that effect,
10 rather than it's going to impact the practice.

11 CHAIRMAN MALMUD: So, the staff would prefer
12 to see wording other than it's -- the current wording
13 which suggests that it might impact practice. Is that
14 correct?

15 MS. BHALLA: That is correct.

16 CHAIRMAN MALMUD: All right. Dr. Zanzonico,
17 do you have a suggestion?

18 MEMBER ZANZONICO: Yes. How about -- so we
19 can say should the NRC -- the recommendation or the vote
20 would be on the following. Should the NRC solicit
21 stakeholder feedback on whether the proposed ME
22 definition for permanent implant brachytherapy is
23 sufficiently clear in language to not adversely effect
24 clinical practice.

25 CHAIRMAN MALMUD: Thank you. Does that meet

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the spirit of the request? That's to NRC staff, the
2 question.

3 MS. BHALLA: We believe we should not bring
4 in the concept of the -- what was that word again?

5 MEMBER ZANZONICO: Well, is the proposed ME
6 definition sufficiently clear in language to not
7 adversely impact clinical practice?

8 MS. BHALLA: We just want to discuss that
9 here for a second.

10 MEMBER LANGHORST: Dr. Malmud, this is Sue
11 Langhorst.

12 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

13 MEMBER LANGHORST: I would like to say that
14 I think the intent here is just to pose a question of
15 the impact of this change, and I think the NRC staff
16 does not, necessarily, have to follow the exact language
17 of a recommendation here, but to ask that type of
18 question, as Neelam was describing to see how this change
19 in medical event definition impacts the practitioners.

20 MEMBER ZANZONICO: This is Pat Zanzonico.
21 I think Dr. Langhorst's point is very well taken. I think
22 we can leave it to the NRC to formulate the exact language
23 of the inquiry but, basically, some feedback should be
24 solicited on the possible clinical impact of the proposed
25 ME definition. But I would feel comfortable leaving it

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 to the NRC to devise the exact language.

2 One other -- if I may, one other point I'd
3 like to raise, and I think it was a point that Dr. Welsh
4 introduced, and it's a very good one. I presume that
5 this solicitation of information would basically be part
6 of in a sense that general public review of the proposed
7 rule so that it should not slow things down. In other
8 words, it would be done in parallel with soliciting other
9 comments, and so forth, rather than in series, so it
10 should not slow things down, which I think is something
11 we all want to avoid. Is that everyone's sense, as well?

12 CHAIRMAN MALMUD: I suspect that it is, Dr.
13 Zanzonico. I don't think anyone would -- well, I
14 shouldn't speak for the rest of the Committee, but I
15 don't believe any of the members of the Committee would
16 object to what you just said. Am I correct in that? I
17 hear no dissension from members of the Committee, so
18 we fully agree with you.

19 MEMBER WELSH: This is Dr. Welsh, if I might
20 just add a quick comment.

21 CHAIRMAN MALMUD: Dr. Zelac?

22 MEMBER WELSH: Welsh.

23 CHAIRMAN MALMUD: Oh, Dr. Welsh.

24 MEMBER WELSH: I suppose I would acquiesce
25 and agree to go along with having this solicitation of

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 input from stakeholders, but I would remind the Committee
2 as a whole that this is essentially the ASTRO definition
3 with a couple of minor modifications. So, although we're
4 not going to have complete unanimity from the entire
5 stakeholder population, this is essentially a society,
6 specifically ASTRO, the ASTRO proposed definition that
7 has been published and discussed repeatedly at the NRC,
8 the various stakeholder meetings, and within the ACMUI
9 and other venues.

10 So, I suppose my point is that although I'm
11 not opposed to seeking additional stakeholder input at
12 this point, to me, I think it's a moot point because
13 we're basically using the ASTRO definition. And my major
14 concern is that if there is any possibility that this
15 is going to slow things down, my vote would be in favor
16 of not allowing anything that could slow things down,
17 to move on.

18 CHAIRMAN MALMUD: Thank you, Dr. Welsh.

19 VICE CHAIRMAN THOMADSEN: And this is Bruce
20 Thomadsen. I will just point out that one of the other
21 major stakeholders was the American Brachytherapy
22 Society, also agreed that they like the ASTRO definition.

23 CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.
24 May we move on? So, we're entrusting the final wording
25 to the NRC, and the Committee is supportive of that.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So, Dr. Zanzonico, we're on to the next item.

2 MS. BHALLA: Well, Dr. Malmud.

3 CHAIRMAN MALMUD: Yes?

4 MS. BHALLA: Yes, this is Neelam Bhalla
5 again. We just -- staff would like to just re-emphasize
6 that we are soliciting -- first of all, a proposed rule
7 is soliciting public -- the whole idea of a proposed
8 rule is to solicit comments from public which would mean
9 licensees. And we have already included in our -- under
10 Section 4 under Discussion, we start with what actions
11 is the NRC taking, and then we are specifically bringing
12 to the public's attention where the changes would be.
13 And, therefore, this particular question to put it like
14 that, if it's going to impact the practice, is not
15 appropriate, so we just want to make that notation here,
16 that the question is already asking the public. And,
17 therefore, we should not be asking a specific question
18 in terms of exactly, you know, how it's going to impact
19 the practice.

20 CHAIRMAN MALMUD: Thank you. Dr. Zanzonico?

21 MEMBER ZANZONICO: Again, I have no
22 objection to leaving it to the NRC Staff to -- in however
23 they typically formulate solicitations for feedback.
24 And it's understood that just requesting public comment
25 is, in effect, accomplishing the same thing. So, I have

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 no objection if the NRC feels it's necessary to eliminate
2 the specific language, that there'll still be
3 opportunity for stakeholders to offer whatever comments
4 they may have without specifically soliciting comments
5 on impact on clinical practice.

6 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.

7 MEMBER LANGHORST: Dr. Malmud, this is Sue
8 Langhorst.

9 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

10 MEMBER LANGHORST: Are we keeping C, or are
11 we not keeping C?

12 CHAIRMAN MALMUD: Dr. Zanzonico?

13 MEMBER ZANZONICO: Good question, Sue. I
14 would suggest that -- well, I would suggest this, let's
15 vote explicitly on retaining Point C as currently worded.
16 And I think the further discussion may be moot once we
17 have a vote, but I would suggest we vote on retaining
18 the language as it's currently presented in the report.

19 MEMBER LANGHORST: This is Sue Langhorst.
20 And I would amend that with recognition that NRC may
21 utilize the language that they think is appropriate for
22 gaining this type of information from its stakeholders.

23 MEMBER ZANZONICO: So, can -- with Dr.
24 Langhorst's amendment, can I then ask for a vote of the
25 members of the Subcommittee?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: Yes, Dr. Zanzonico. Do the
2 members of the Subcommittee approve?

3 MEMBER LANGHORST: I approve.

4 CHAIRMAN MALMUD: Any disapproval or
5 abstentions? You have unanimity again. Now, should we
6 take it to the whole Committee, Dr. Zanzonico?

7 MEMBER ZANZONICO: Yes, please.

8 CHAIRMAN MALMUD: Now members of the entire
9 Committee that have voting privileges, is there anyone
10 opposed to this motion which has been approved by the
11 Subcommittee? Are there any abstentions? I will assume,
12 therefore, that all the other votes are positive. Once
13 again you have unanimity, Dr. Zanzonico.

14 MEMBER ZANZONICO: Very good, thank you.

15 So, the next item, this would be Item 1D.
16 And I think this is very explicit, and that is that the
17 Subcommittee recommends that the proposed rule for
18 redefining MEs in permanent implant brachytherapy be
19 designated as Compatibility Category B rather than C.

20 CHAIRMAN MALMUD: Thank you. That's a motion
21 from the Subcommittee?

22 MEMBER ZANZONICO: Correct.

23 CHAIRMAN MALMUD: And the Subcommittee
24 members have approved that thus far.

25 MEMBER ZANZONICO: Well, we can have a vote.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: Okay. All in favor
2 -- these are members of the Subcommittee. All in favor?

3 (Chorus of ayes.)

4 CHAIRMAN MALMUD: Any opposed? Any
5 abstentions?

6 (No response.)

7 CHAIRMAN MALMUD: There's unanimity. May we
8 take that now to the whole Committee? All in favor?

9 MEMBER LANGHORST: Dr. Malmud, this is Sue
10 Langhorst.

11 CHAIRMAN MALMUD: Dr. Langhorst?

12 MEMBER LANGHORST: Yes, you may want to ask
13 the staff for their opinion on this before it goes to
14 the whole Committee.

15 CHAIRMAN MALMUD: Thank you for reminding
16 me, Dr. Langhorst. The opinion of the staff?

17 MR. EINBERG: Yes. This is Chris Einberg.
18 We don't have anybody from the Agreement States Program
19 here, so we have no comment at this point.

20 CHAIRMAN MALMUD: Thank you, Chris. Members
21 of the Committee as a whole, any objections? Any
22 abstentions?

23 (No response.)

24 CHAIRMAN MALMUD: Hearing none, it's
25 unanimous again. Thank you, and we'll move on to the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 next item. Dr. Zanzonico.

2 MEMBER ZANZONICO: Yes. So, this would
3 -- and I think this is -- I can't imagine this would
4 be contentious, Item 1E. And the recommendation would
5 be to replace the phrasing in the literature or to the
6 literature in terms of support for the 5 cubic centimeter
7 of contiguous normal tissue provision of the ME
8 definition, to replace the "literature" phrasing with
9 the specific references cited, that's Nag, et al 2004.
10 So, can the Subcommittee -- would the members of the
11 Subcommittee vote on approving that revision?

12 CHAIRMAN MALMUD: All the members of the
13 Subcommittee who approve please say aye.

14 (Chorus of ayes.)

15 CHAIRMAN MALMUD: Any opposed? Any
16 abstentions?

17 (No response.)

18 CHAIRMAN MALMUD: You've achieved unanimity
19 again, Dr. Zanzonico. If we may, any comments from NRC
20 Staff?

21 MS. BHALLA: Yes, this is Neelam Bhalla. We
22 just want to thank the Committee, the Subcommittee on
23 this.

24 CHAIRMAN MALMUD: Thank you, Ms. Bhalla. Now
25 take it to the entire Committee. All in favor?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

(Chorus of ayes.)

CHAIRMAN MALMUD: Any objections? Any abstentions?

(No response.)

CHAIRMAN MALMUD: Once again unanimity. Thank you, Dr. Zanzonico. Next item?

MEMBER ZANZONICO: Okay. So, now we're to Item 2, and this is on the training and experience issue. And the first actionable item is 2B. And the basic recommendation is to eliminate the explicit requirement for supervised work experience on the elution of generators with the understanding that -- not that that's not an important consideration, but that it's adequately covered by the other more general training and experience requirements. We just are recommending, in other words, not to separate out this one particular item.

CHAIRMAN MALMUD: All right. Is there discussion of this from other members of your Subcommittee?

MEMBER LANGHORST: This is Sue Langhorst, just a real minor thing, Pat. On those line numbers they should --

MEMBER ZANZONICO: Yes.

MEMBER LANGHORST: -- be 1447 and 1448.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER ZANZONICO: Correct. Thank you, Sue.

2 MEMBER LANGHORST: Okay, thank you.

3 MEMBER MATTMULLER: Dr. Malmud, this is
4 Steve Mattmuller.

5 CHAIRMAN MALMUD: Yes, Steve?

6 MEMBER MATTMULLER: I'm -- maybe I'm asking
7 for help from the NRC Staff. I'm not sure, because as
8 I read the proposed reg, it was really more as far as
9 in regards to generator training, was that it could be
10 provided by an authorized nuclear pharmacist, or an ANP.
11 And I think the Subcommittee now has gone an additional
12 step of trying to create a special category that only
13 if the licensee has a generator should then that
14 authorized user have this specialized training, which
15 is where I think it's gone. And at this point, I'm not
16 sure I agree with that. Especially from a perspective
17 that even though the vast majority of sites do have
18 generators, a lot of those same sites still get bulk
19 technetium in the afternoon for evening emergency
20 procedures using such kits as MAA and/or Ultra Tag. So,
21 I mean, personally I believe it's important that the
22 authorized user get this type of training. Thank you.

23 CHAIRMAN MALMUD: Thank you. Any comments
24 with regard to Steve Mattmuller's comments?

25 MEMBER SULEIMAN: This is Orhan Suleiman.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: Dr. Suleiman.

2 MEMBER SULEIMAN: I'm more concerned with
3 -- I sort of agree with the Subcommittee in that we don't
4 want to burden authorized users who may not be using
5 the generator with that sort of training. However, I'm
6 more concerned with the flip side of that, that people
7 who actually use generators, based on our observations
8 over the last few years when we've had problems in the
9 field, apparently don't understand how generators work.
10 And there have been some safety issues because of that,
11 so I don't know if it comes here, but I sympathize with
12 the need not to burden people who don't use the generators
13 with learning how to use them, but we'll discuss this
14 latter issue when we get further on into the Subcommittee
15 report.

16 CHAIRMAN MALMUD: Thank you for your
17 comments, Dr. Suleiman.

18 MEMBER GUIBERTEAU: Dr. Malmud.

19 CHAIRMAN MALMUD: Yes?

20 MEMBER GUIBERTEAU: This is Mickey
21 Guiberteau.

22 CHAIRMAN MALMUD: Yes, Dr. Guiberteau.

23 MEMBER GUIBERTEAU: You know, I think this
24 is a -- as I have read in a number of emails and articles,
25 this is -- the issue of generators has morphed from a

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 rather simple device to one, you know, a concept that's
2 become very complex. It is exceedingly large and growing
3 burden on residencies in nuclear medicine, as well as
4 diagnostic radiology, nuclear radiology, and now even
5 cardiology with intimate contact and experience with
6 generators that will likely never be used by the AUs
7 practicing clinical medicine.

8 I think this is a very important issue, and
9 I also think to Orhan's point that while we may be
10 training and getting experience for everyone, that
11 experience might be somewhat -- terms of bolstering
12 confidence in AUs, might be a little bit unrealistic
13 simply because in real practice it might give us the
14 false sense that people have intimate contact with all
15 sorts of generators when they really don't when they
16 go in practice. So, I mean, I think -- I agree with the
17 Subcommittee. I think that this doesn't -- I agree that
18 this part of the proposed rule is really too much of
19 a burden and likely doesn't accomplish what we would
20 like it to accomplish.

21 CHAIRMAN MALMUD: Thank you for your
22 comment, Dr. Guiberteau. Dr. Suleiman, do you wish to
23 comment on that?

24 MEMBER SULEIMAN: I sort of concur with what
25 he said. So, on this part of the Subcommittee report,

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I also agree. Why burden an authorized user with
2 operating a generator when that individual may not
3 operate the generator, and it may lead to a false sense
4 of knowing how to operate it.

5 CHAIRMAN MALMUD: All right, thank you.

6 MEMBER PALESTRO: Dr. Malmud, Chris
7 Palestro. May I speak?

8 CHAIRMAN MALMUD: Yes, please.

9 MEMBER PALESTRO: Okay. I certainly agree
10 with the Subcommittee's comment. I think the number of
11 sites that use generators are few to begin with nowadays,
12 and probably decreasing; that to insist that every AU
13 receive work experience in a generator is probably
14 impractical, and not very useful. And I would think that
15 it would be more appropriate for those AUs who are using
16 generators to receive generator-specific training for
17 the type of generator that they use.

18 CHAIRMAN MALMUD: Thank you for that
19 comment. I suspect a number of us agree with you. Dr.
20 Zanzonico?

21 MEMBER VAN DECKER: Can I add one other
22 thought, one other voice? This is Bill Van Decker.

23 CHAIRMAN MALMUD: Yes, Dr. Van Decker.

24 MEMBER VAN DECKER: You know, I think that
25 I would agree with the concepts of some of my other

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 colleagues here. I think that, obviously, what is a
2 generator and how does a generator work is a general
3 topic that everyone needs to know as part of the AU
4 training experience. It would indeed be true that, you
5 know, if you're going to be using a generator you should
6 be pretty well versed in what that generator is,
7 recognizing that there may be newer generator systems
8 coming on line in the future. I think the only thing
9 for us to keep in the back of our minds is -- and I think
10 Dr. Suleiman pointed this out as we get further on, what
11 does that generator-specific training look like, when
12 one adds a modality to one's practice, is it really just
13 the learning of the generator, which I think it should
14 be rather than just the Radiation Safety principles of
15 a generator which is general knowledge in the AU
16 category. And, certainly, we have models for adding
17 modalities and a variety of other regs especially in
18 Radiation Onc-type realm, but I just think it's something
19 for us to keep in mind as we move forward.

20 CHAIRMAN MALMUD: Thank you for that
21 comment. Dr. Zanzonico, we're back to you.

22 MEMBER ZANZONICO: Yes. So, I think the
23 recommendation then becomes --

24 MS. BHALLA: Excuse me, Dr. Malmud.

25 MEMBER ZANZONICO: Yes?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

1 MS. BHALLA: This is Neelam Bhalla, and I
2 just wanted to say that we -- when we started this
3 rulemaking it was based on what are called these user
4 need memos. It's the need that the implementing division
5 or Program office has to revise these regulations. And
6 in that the need was expressed that this training could
7 be provided. It's in the existing regs, and the training
8 could be provided by authorized nuclear pharmacists
9 along with the other of the authorized users. So, as
10 you know, the rule is due to the Commission very soon.
11 And, therefore, this will be changing the scope of the
12 rulemaking. And, therefore, we just wanted you to know
13 that the request was only to allow the nuclear
14 pharmacists to be able to give this training. So,
15 therefore, the rule is being amended to do that, and
16 we may not be able to at this point go over if AU need
17 that training, of it's possible for them, because that's
18 like starting an issue. And at this point, it's -- not
19 be able to entertain it.

20 MEMBER ZANZONICO: This is Pat Zanzonico.
21 So, if I can understand the intent of this passage in
22 the proposed rule is not to require, necessarily,
23 supervised work experience on generator elution and so
24 forth, but if such training -- if such supervised work
25 experience is provided, it could be provided by an

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 authorized nuclear pharmacist, as well as an authorized
2 user. Is that correct?

3 MS. BHALLA: Yes. What is correct is that
4 it's in the existing training requirement, so the fact
5 that should they be trained in that aspect, that was
6 not on the table, but it was who could provide that
7 training. So, the reg says -- we are amending the regs
8 that this training can be provided by the authorized
9 pharmacists, because they have as much know-how in this
10 system as anybody else. So, no, we are not changing the
11 current training requirement per se, but only who can
12 actually give that training.

13 MEMBER ZANZONICO: Okay, understood. So, I
14 would -- this is Pat Zanzonico again. I think given that,
15 I would concede that I misunderstood what was being
16 proposed. And in that case, I would suggest withdrawing
17 this recommendation.

18 MEMBER LANGHORST: Pat, this is Sue
19 Langhorst. I disagree with you. I would -- the questions
20 are there. It's not really any recommendation other than
21 questions as to why this is necessary. And I think based
22 on some of the comments of our colleagues and on the
23 Committee, it's a fair question to ask, and I would
24 recommend that it stay in here.

25 MEMBER ZANZONICO: Sue, in that -- this is

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Pat Zanzonico again. In that case, certainly we can leave
2 our report as is with comments and questions, some
3 actionable items, some non-actionable items. Would you
4 feel comfortable just leaving this particular item as
5 is without couching it in the form of a formal
6 recommendation?

7 MEMBER LANGHORST: Yes, I would. There is
8 no real recommendation here of ACMUI. It's just raising
9 those questions, and proposing an alternative of how
10 NRC Staff could handle this type of thing in the future.

11 MEMBER ZANZONICO: Understood.

12 MEMBER GUIBERTEAU: Pat.

13 MEMBER ZANZONICO: Yes?

14 MEMBER GUIBERTEAU: This is Mickey
15 Guiberteau, may I offer a comment?

16 MEMBER ZANZONICO: Please.

17 MEMBER GUIBERTEAU: You know, I -- putting
18 aside for a moment whether or not AUs in 298 need
19 generator on-hands experience, if it is going to be
20 continued to be required, which is what I understood
21 is preferred, it is very important that authorized
22 pharmacists be able to provide this, because in many
23 institutions the only place they're able to get it is
24 by sending their residents to a commercial pharmacy where
25 a pharmacist, a nuclear pharmacist is the person

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 providing the training. And in the past that has been
2 somewhat questioned since in most of the rule you have
3 to have someone providing that training who is actually
4 performing -- an AU in the same areas, clinical areas
5 of the rule. So, I don't want to let --I would prefer
6 that not be lost in this because if we're keeping the
7 training requirement the same, it would be very helpful
8 to know who we can go to, to whom we may go to get this
9 training.

10 MEMBER ZANZONICO: Understood. My
11 understanding is that the proposed rules would allow
12 nuclear pharmacists to provide the training, and at the
13 same time I think in retaining the language in Item 2B,
14 as Sue suggests, isn't contrary to that.

15 MEMBER GUIBERTEAU: All right.

16 CHAIRMAN MALMUD: Therefore, I understand
17 that we will leave it in, recognizing that it will not
18 be acted upon, but it will certainly convey the spirit
19 of the ACMUI and the Subcommittee to whoever reads it.

20 MEMBER ZANZONICO: Pat Zanzonico. That would
21 be my suggestion and my understanding, as well.

22 CHAIRMAN MALMUD: Thank you. And do we have
23 approval of the members of the Subcommittee for this?
24 Any objections or abstentions? If not, are there any
25 objections or abstentions from the Committee having

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 heard the comments of NRC staff already?

2 (No response.)

3 CHAIRMAN MALMUD: Hearing none I assume that
4 it's, therefore, approved unanimously.

5 MR. EINBERG: Dr. Malmud, Chris Einberg
6 here.

7 CHAIRMAN MALMUD: Yes, Chris.

8 MR. EINBERG: Does the Committee want to
9 endorse the current language right now also, that the
10 NRC Staff has proposed in the rule to allow the nuclear
11 pharmacist to do the training?

12 CHAIRMAN MALMUD: Yes, that was -- I believe
13 that was what Dr. Zanzonico was proposing. Am I correct,
14 Pat?

15 MEMBER ZANZONICO: Well, actually, I was not
16 thinking of this as a -- we're not calling an actionable
17 item, in other words, a votable item at all. But I think
18 that's not unreasonable. So, yes, we could have a vote
19 on the language, and it's in lines 1447 to 1448 on page
20 48 that says, "ANPs have the T&E to provide the supervised
21 work experience for AUs on the elution of generators."
22 Again, as was pointed out, it's simply allowing ANPs,
23 it's authorizing ANPs to provide that training.

24 CHAIRMAN MALMUD: All members of the
25 Subcommittee in favor, please say aye.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

(Chorus of ayes.)

CHAIRMAN MALMUD: Any opposed? Any abstentions?

(No response.)

CHAIRMAN MALMUD: All right. That's the motion of the Subcommittee. Does NRC staff wish to make a comment before we take it to the whole Committee?

MS. BHALLA: No, we are fine, thank you.

CHAIRMAN MALMUD: Thank you. The entire Committee, we'll consider this a motion from the members of the Subcommittee. All in favor?

(Chorus of ayes.)

CHAIRMAN MALMUD: Any objections? Any abstentions?

(No response.)

CHAIRMAN MALMUD: Hearing neither objections nor abstentions, it passes unanimously. Thank you. We'll move on to the next item.

MEMBER ZANZONICO: So the next item is Item 2-C. We're still on training and experience. And it's a proposed change in language. And the language, and this appears at multiple points in the proposed rule.

The current language in the proposed rule is that preceptors would attest that trainees or candidates have satisfactorily fulfilled the training

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 and experience requirements consistent with achieving,
2 I'm sorry.

3 What the proposed rule said, have
4 satisfactorily completed the necessary training and
5 experience requirements, and has achieved a level of
6 competency sufficient to function independently in the
7 position for which the authorization is sought. That's
8 the current language.

9 The language being proposed, the
10 alternative language being proposed is, "Has
11 satisfactorily fulfilled the training and experience
12 requirements consistent with achieving a level of
13 competency sufficient to function independently in the
14 position for which the authorization is sought."

15 So again, the distinction is the preceptor
16 attesting that the candidate has achieved a level of
17 competency. The alternate language being proposed is
18 simply asking the preceptor to attest that the candidate
19 has completed training and experience consistent with
20 achieving that competency. So what we're voting on is
21 replacing that current language with the alternative
22 language.

23 MS. BHALLA: Yes, Dr. Malmud?

24 CHAIRMAN MALMUD: Yes.

25 MS. BHALLA: The staff wants to speak on

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 this a little bit.

2 CHAIRMAN MALMUD: Please do.

3 MS. BHALLA: And Susan Chidakel from NRC
4 is going to. Because I think it's somewhat
5 misunderstood.

6 MS. CHIDAKEL: Hi. Thank you for letting
7 me interject here. I think you have misread the language.
8 The language that you're talking about, you've taken
9 out of our summary of what we're changing.

10 And what the language that you're talking
11 about, it says the attestation must state that the
12 individual has satisfactorily completed. That's the
13 language that's in the rule now.

14 We're proposing to take that language out
15 completely and change that whole thing, and take out
16 the reference to competence.

17 If you look at the actual rule text, for
18 example if you look at Page 98 or 99 for actual rule
19 text that's in the rule itself, you'll see that
20 competence language is not in there.

21 So I think you've misunderstood what we were
22 doing here. We weren't trying to tell you what we were
23 going to try to change to put in something about
24 competence. We were summarizing the state of affairs
25 right now.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER ZANZONICO: In that case, this is
2 Pat Zanzonico, in that case then I didn't misunderstand.

3 MS. CHIDAKEL: You did not misunderstand?

4 MEMBER ZANZONICO: No, I did, based on what
5 you're just telling me now. It was my understanding,
6 clearly mistaken, that this was the language in the new
7 language.

8 MS. CHIDAKEL: No. Take a look, for example,
9 at Page 99. If you look at B-2, you'll see a sample of
10 what -- this is for the authorized nuclear pharmacist.
11 You'll see a sample of what the preceptor is going to
12 be attesting to now, in the new proposed rule, just as
13 an example.

14 And you can look at several sections. You
15 can see the same thing on Page 98, with regard to the
16 authorized medical physicist. I just picked out a couple
17 at random.

18 MEMBER ZANZONICO: I don't know if you have
19 the line numbers. Is it possible you can identify the
20 line numbers?

21 MS. CHIDAKEL: On Page 98 it starts on, B
22 starts on 2899. And then it's on 2900, it says too, have
23 obtained written attestation. Do you see that there?

24 MEMBER ZANZONICO: Right.

25 MS. CHIDAKEL: Okay. Then just keep reading

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 on down.

2 MEMBER ZANZONICO: Okay.

3 (Off the record comments)

4 MS. BHALLA: 2901.

5 MS. CHIDAKEL: I'm sorry?

6 MS. BHALLA: 2901.

7 MS. CHIDAKEL: Did I get the wrong line?

8 Here it is, right. Thank you, Neelam, 2901, "Is able
9 to independently fulfill the radiation safety related
10 duties as an authorized medical physicist for each type
11 of therapeutic medical unit for which the individual,"
12 et cetera, et cetera, et cetera.

13 And you see there's nothing in here about
14 competence. And even more clearly, if you flip the page
15 to Page 99, and look at line 2927 --

16 MEMBER ZANZONICO: Yes.

17 MS. CHIDAKEL: Two, "Has obtained written
18 attestation signed by the preceptor authorized nuclear
19 pharmacist, the individual has satisfactorily completed
20 the requirements in B-1, and is able to independently
21 fulfill the radiation safety related duties of an
22 authorized nuclear pharmacist." There's nothing in
23 here about competency anymore.

24 MEMBER ZANZONICO: Understood.

25 CHAIRMAN MALMUD: This is Malmud, that's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 wonderful. Because we've struggled with that term for
2 a long time, and very much appreciate the wording that's
3 now in the document.

4 MEMBER ZANZONICO: That is why, this is Pat
5 Zanzonico, I acknowledge my misunderstanding. And on
6 that basis, am happy to withdraw consideration of this
7 recommendation.

8 CHAIRMAN MALMUD: Thank you.

9 MEMBER ZANZONICO: Although having said
10 that, I think it emphasizes the need for a more explicit
11 executive summary type statement.

12 CHAIRMAN MALMUD: This is Malmud, were you
13 referring to something specific?

14 MEMBER ZANZONICO: No, again, it was just,
15 I felt I read the document carefully, and this other
16 language appeared so frequently that it was difficult
17 to not infer that this might be the --

18 (Telephone interference)

19 CHAIRMAN MALMUD: Shall we move on? Pat?

20 MEMBER ZANZONICO: Yes, I think we can move
21 on. So I think Item 2-C is now moot, in that the language
22 referring to attestation of competency actually does
23 not appear in the proposed rule.

24 CHAIRMAN MALMUD: Thank you. That's an
25 enormous accomplishment. Because we've been struggling

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 with this, NRC's been struggling with this with us, for
2 a long time. And that alone is quite an accomplishment.

3 MEMBER ZANZONICO: Yes, agreed.

4 CHAIRMAN MALMUD: And we thank the NRC staff
5 as well the wisdom of the ACMUI members. All right, then
6 we move on.

7 MEMBER LANGHORST: Dr. Malmud, this is Sue
8 Langhorst.

9 CHAIRMAN MALMUD: Yes, Doctor Langhorst.

10 MEMBER LANGHORST: I think maybe we should
11 just vote to make sure that we are taking that out.

12 CHAIRMAN MALMUD: All right. Is that a
13 motion, Doctor Langhorst?

14 MEMBER LANGHORST: Yes, it is.

15 CHAIRMAN MALMUD: Is it seconded?

16 MEMBER MATTMULLER: It's Steve Mattmuller.
17 Yes, second.

18 CHAIRMAN MALMUD: Thank you. Any further
19 discussion of the item?

20 MEMBER GUIBERTEAU: Doctor Malmud?

21 CHAIRMAN MALMUD: Yes, who is this?

22 MEMBER GUIBERTEAU: This is Mickey
23 Guiberteau. I'm sorry, I just got back --

24 CHAIRMAN MALMUD: Yes, Mr. Guiberteau.

25 MEMBER GUIBERTEAU: -- back on the call.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 I hear that we're taking this out. I just wanted to make
2 certain that the sub-committee is, the word competency,
3 as has been said, has always been an issue.

4 But the statement that was read from the
5 rule, and the statement that is here proposed is a bit
6 different in that the proposed rule really indicates
7 that there should be an attestation that the trainee
8 has fulfilled the T&E requirements, and is able to
9 function independently in the position for the
10 authorization.

11 So there is still a judgment involved, as
12 opposed to the language here, which simply says that
13 the training has been fulfilled, and that training is
14 consistent with achieving a level, an ability.

15 So I realize it's small, but there may be
16 some who feel like making any sort of judgment regarding
17 a trainee, as to how they may perform in practice, is
18 not acceptable. And I just want to point that out before
19 you eliminate this.

20 CHAIRMAN MALMUD: If you take a look at Page
21 99, lines 2927 through 2930, are those lines acceptable
22 to you, Doctor Guiberteau?

23 MEMBER GUIBERTEAU: They're acceptable to
24 me. And to be honest, I think they're fine. But I'm
25 just pointing out that there is a difference that what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 is read, and I don't have that in front of me
2 unfortunately. I'm not in a location where --

3 CHAIRMAN MALMUD: Oh, I'll read it to you
4 if I may.

5 MEMBER GUIBERTEAU: All right, right.

6 CHAIRMAN MALMUD: "Has obtained written
7 attestation, signed by a preceptor authorized, in this
8 case nuclear pharmacist, that the individual has
9 satisfactorily completed the requirements in Paragraph
10 D-1 of this section, and is able to independently fulfill
11 the radiation safety related duties as an authorized
12 nuclear pharmacist."

13 MEMBER GUIBERTEAU: Right. Personally, I
14 have no issue with it. I'm only pointing out that there
15 is a judgment as to whether a person is able to do the
16 job, as opposed to what the statement that the
17 sub-committee has written, which said that the training
18 has been achieved, and that training is consistent with
19 an ability, but doesn't require a judgment.

20 And I'm just saying that in the past there
21 was the issue of judging competency. In this case, it's
22 judging an ability. And if we're fine with that, then
23 I personally am fine with that.

24 But I do know that there have been some
25 objections to a judgment of any sort on the part of future

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 performance by a trainee by some of the authorized users
2 who provide these statements. So I just want to make
3 sure that everyone is clear on that before we move on.

4 CHAIRMAN MALMUD: Yes, I understand your
5 concern, Doctor Guiberteau. Are there others who wish
6 to comment about this?

7 MEMBER ZANZONICO: This is Pat Zanzonico.
8 I think the point is well taken. And the intent in
9 my suggested language was to eliminate entirely the
10 judgment call.

11 So if we amended this language, made a
12 recommendation to amend this language, say in Line 2929
13 and elsewhere, and change "and is able to independently
14 fulfill," change that, consistent with being able to
15 independently fulfill, or consistent with the ability
16 to independently fulfill, et cetera. That would seem
17 to eliminate any judgment call.

18 MEMBER GUIBERTEAU: Dr. Malmud?

19 CHAIRMAN MALMUD: Yes.

20 MEMBER GUIBERTEAU: This is Mickey
21 Guiberteau.

22 CHAIRMAN MALMUD: Yes.

23 MEMBER GUIBERTEAU: I think that language
24 that has been proposed, quite frankly, is excellent,
25 by the sub-committee. And I think it would be acceptable

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 to a broader group of authorized users who are serving
2 as preceptors. And so I would support that.

3 CHAIRMAN MALMUD: You would support the
4 current language, Doctor Guiberteau?

5 MEMBER GUIBERTEAU: No. Although I
6 personally don't have any issue with the proposed rule,
7 I do think that the language proposed by the
8 sub-committee is preferable to a wider spectrum of
9 authorized users acting as preceptors for trainings.
10 And so personally I would support the language proposed
11 by the sub-committee, as an ACMUI member.

12 CHAIRMAN MALMUD: All right. So we have a
13 comment from Doctor Guiberteau, a member of the ACMUI,
14 that the other language is preferable to that which is
15 in Line 2828 and 2829, specifically 2929. Dr. Zanzonico?

16 MEMBER ZANZONICO: Well, let me just
17 reiterate then what that language is. The language
18 would be, "Has satisfactorily fulfilled the training
19 and experience requirements consistent with achieving
20 a level of competency sufficient to function
21 independently in the position for which authorization
22 is sought."

23 And the key distinction in that language
24 is the preceptor is simply attesting to achieving
25 training and experience consistent with. So there's no

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 judgment call at all.

2 I think that's preferable. I think the
3 language which most decisively eliminates the judgment
4 call on the part of the preceptor is preferred.

5 CHAIRMAN MALMUD: You have re-entered the
6 word competency, though.

7 MEMBER ZANZONICO: Well, good point. Yes.

8 MEMBER GUIBERTEAU: This is Mickey
9 Guiberteau. I think the word competency is also a loaded
10 term that many authorized users acting as preceptors
11 are uncomfortable with.

12 I totally agree with their position. I do
13 think that the language that the sub-committee has
14 proposed, that if we use the language that you had amended
15 that language to a moment ago, by using ability as
16 consistent with achieving an ability to act, is
17 preferable to competency.

18 MEMBER ZANZONICO: Right, I agree, I agree.

19 MEMBER LANGHORST: Doctor Malmud, this is
20 Sue Langhorst.

21 CHAIRMAN MALMUD: Doctor Langhorst, yes.

22 MEMBER LANGHORST: Based on this discussion,
23 I will remove my motion to remove this paragraph, I guess.

24 CHAIRMAN MALMUD: You want to remove the
25 paragraph beginning on Line 2927, which relates to the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 nuclear pharmacists?

2 MEMBER LANGHORST: I'm sorry, no. We're
3 talking about this paragraph 2-C, where I had made motion
4 to remove that paragraph. And so I was wanting to remove
5 my motion because it sounds like we want to keep the
6 paragraph and modify the language.

7 MEMBER ZANZONICO: Can I offer the
8 re-revised language, based on Doctor Guiberteau's
9 comment?

10 CHAIRMAN MALMUD: Please do, Doctor
11 Zanzonico.

12 MEMBER ZANZONICO: Okay. It would be, "Has
13 satisfactorily fulfilled the training and experience
14 requirements consistent with being able to independently
15 function in the position for which authorization is
16 sought."

17 CHAIRMAN MALMUD: Is that a motion, Doctor
18 Zanzonico?

19 MEMBER ZANZONICO: Yes, let's call it a
20 motion.

21 CHAIRMAN MALMUD: Do you want to put that
22 before your sub-committee?

23 MEMBER ZANZONICO: Yes. So let me re-read
24 that. The motion would be to use the language, "Has
25 satisfactorily fulfilled the training and experience

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 requirements consistent with being able to independently
2 function in the position for which authorization is
3 sought."

4 MEMBER GUIBERTEAU: I like it.

5 MEMBER LANGHORST: This is Sue Langhorst.

6 I like it too. But I think we need to clarify that there's
7 more changes needed in that paragraph to get rid of the
8 confusion of what you thought was the language.

9 MEMBER ZANZONICO: Agreed. No, I agree. I
10 would revise our report. This was a draft report, the
11 sub-committee draft report. I will revise it at a number
12 of points, including clarifying my confusion on what
13 I thought was being proposed versus what actually is
14 being proposed.

15 VICE CHAIRMAN THOMADSEN: Pat, this is Bruce
16 Thomadsen. Could you please repeat the current motion?

17 MEMBER ZANZONICO: Okay. The current motion
18 would be to replace, in the proposed rule, to replace
19 language that states a candidate is able to independently
20 fulfill the radiation safety related duties for which
21 authorization is being sought -- again, whether it's
22 a nuclear pharmacist, authorized user, et cetera -- to
23 change that language, "Is able to independently fulfill
24 the radiation safety related duties," to "Has
25 satisfactorily fulfilled the training and experience

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 requirements consistent with the ability to
2 independently function in the position for which
3 authorization is sought."

4 VICE CHAIRMAN THOMADSEN: Thank you.

5 MS. BHALLA: Doctor Malmud?

6 CHAIRMAN MALMUD: Yes, I was just about to
7 ask you for NRC staff's opinion about this.

8 MS. BHALLA: Yes. At the ACMUI meeting held
9 in April of 2011, we discussed this very issue about
10 the specific language. So the language that we have here
11 is the one that was approved, or recommended by the ACMUI
12 at that time.

13 And we just believe that there isn't a whole
14 lot of different words being proposed now. So just
15 wanted to say that what we have right now is what was
16 approved by the ACMUI back in April of 2011.

17 CHAIRMAN MALMUD: Yes, this is Malmud. I have
18 the same recollection as you do. You have the advantage
19 as well of having the minutes of that meeting. And we
20 struggled with it at that time.

21 And we had hoped that the NRC would be
22 willing to accept terminology that eliminated the word
23 consistent. And we achieved that in the wording that
24 you have in the current document.

25 I truly don't see much difference in what

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Doctor Zanzonico is proposing, and in what's on paper.

2 Because if the concern is that someone may be sued for
3 the actions of his or her trainee some years later, I
4 don't see a difference between the wording that was
5 proposed and the wording that's in here.

6 But this is just one man's opinion. And the
7 wording of consistent with being able to independently,
8 and being able to independently function, isn't much
9 of a difference to me.

10 When we train people, we recognize that not
11 only will they be learning a lot more when they're out
12 in the field than they learned during the training
13 program because of the advances that are occurring
14 constantly, but that some of the things that they were
15 trained with, that are not used frequently, are forgotten
16 or need to be re-trained.

17 So I think that the wording that's been
18 achieved in the current document represents that which
19 we worked for, for a period of several years, at least.

20 However, if the committee feels that
21 there's an improvement to be made with this, then
22 obviously we'll recognize it. Excuse me. I don't see
23 the difference between the two.

24 MEMBER WELSH: Dr. Malmud?

25 CHAIRMAN MALMUD: Yes, I hear two voices.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER WELSH: Jim Welsh here, if I might.

2 CHAIRMAN MALMUD: Doctor Welsh.

3 MEMBER WELSH: If I recall correctly, please
4 correct me if not accurate, it was not the word
5 consistent, but the word competence that was most
6 offensive.

7 CHAIRMAN MALMUD: You're correct, you're
8 correct. It was the word competence. That was my slip.
9 It was the word competence.

10 MEMBER WELSH: The current iteration,
11 although the words may not be exact, seems to be in the
12 correct spirit.

13 CHAIRMAN MALMUD: Yes.

14 MEMBER WELSH: It just is a matter of
15 word-smithing to make sure that we don't have the word
16 competence, which leaves us liable as preceptors, or
17 even the board as an organization, to say that this person
18 is qualified and is competent because he passed the
19 boards. That omission of the word competence is what
20 we are seeking today.

21 CHAIRMAN MALMUD: Yes, you are correct. I
22 mis-spoke in this last statement. I earlier said it was
23 the word competence that was the issue of conflict, and
24 it was the issue of conflict. It appears to be resolved,
25 but I think someone else wanted to make a comment as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 well.

2 MEMBER PALESTRO: Yes, Chris Palestro.

3 CHAIRMAN MALMUD: Yes, Doctor Palestro.

4 MEMBER PALESTRO: I have to agree with you,
5 Leon, in reading the two sections. I couldn't really
6 appreciate a difference. One may sound more palatable
7 than the other, or less intimidating. But I'm just not
8 sure that there's significant difference between the
9 two.

10 MEMBER ZANZONICO: This is Pat Zanzoniko.
11 Given this discussion, I think the language using the
12 word consistent is preferable. Having said that, I have
13 no strong objection whatsoever to the language as it's,
14 the new language, currently in the proposed rule.

15 And I would have no hesitation about asking
16 the sub-committee, and then the full committee, for a
17 vote on the language as it appears in the, the new
18 language as it appears in the proposed rule.

19 CHAIRMAN MALMUD: So is that proposal to your
20 committee that the current language as printed in the
21 document, without change, is acceptable?

22 MEMBER ZANZONICO: Yes. That would be asking
23 for a vote on that recommendation.

24 CHAIRMAN MALMUD: Does the rest of the
25 sub-committee agree with Doctor Zanzonico?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER PALESTRO: Yes.

2 MEMBER LANGHORST: Yes.

3 CHAIRMAN MALMUD: Any objections to it? Any
4 abstentions? So you have unanimity once again, Doctor
5 Zanzonico. Now we'll present that to the entire committee
6 and ask for their approval of the wording as it's printed
7 in the current document, an example of which is on Lines
8 2927 through 2930, for approval.

9 Anyone object? Does anyone abstain?
10 Hearing neither objection nor abstentions, we will
11 declare it unanimous. I must tell you that I have to
12 congratulate you, Doctor Zanzonico, and members of the
13 committee.

14 Because you've achieved something we've
15 been struggling with for three, if not four, years.
16 Thank you very much. We will move on to the next numbered
17 item if we may.

18 MEMBER ZANZONICO: Yes. And this was Item
19 2-D. And the issue, as I tried to state it initially,
20 seemed to be that the proposed rule was parsing, for
21 lack of a better term, authorization to use different
22 types of radionuclides and radiopharmaceuticals that
23 is more restrictive than what's in the current rule.

24 Again, in Lines 1503 to 1508 it states, "The
25 current regulations include a broad category for

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 parental administration of any other radionuclide."
2 This fourth category would be removed as any new parental
3 administration of radionuclides not listed in this
4 paragraph would be regulated under 35-1000.

5 This approach would allow the NRC to review
6 each new proposed radionuclide for parental
7 administration and determine the appropriate P&E for
8 its use.

9 Now, the NRC staff will correct me if I
10 misunderstood. But my inference is that this new proposed
11 rule would allow the NRC the latitude to review each new
12 radiopharmaceutical, or radionuclide, on a case by case
13 basis, which just seems far more onerous, potentially,
14 than the current rule, which at least has broad categories
15 of types of radionuclides. So again, I think the
16 sub-committee feels that the different classes of
17 radionuclides and radiopharmaceuticals, in terms of
18 clinical applications, radiation safety, radiation
19 biology, are far more similar than they are different,
20 and that a radionuclide by radionuclide, or
21 radiopharmaceutical by radiopharmaceutical
22 authorization is really excessive and unnecessary.

23 And so we feel that practitioners who have
24 the requisite training in engineering, and experience,
25 rather, to safely and effectively utilize any one, any

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 class of diagnostic and therapeutic radionuclides have
2 the training and experience to utilize all of them.

3 CHAIRMAN MALMUD: That's been the assumption
4 until now, that if we're competent to use a class of
5 radiopharmaceuticals, or radionuclides, that we are able
6 to handle others as they come.

7 MEMBER ZANZONICO: Right. If I could ask the
8 NRC staff, am I misunderstanding the meaning of the
9 language, of the relevant language in the proposed rule?

10 CHAIRMAN MALMUD: That's a question from
11 Doctor Zanzonico to NRC staff.

12 Dr. Howe, are you on the line?

13 DR. HOWE: Yes, I am.

14 CHAIRMAN MALMUD: Would you like to comment?

15 DR. HOWE: Okay. The intent was to break the
16 radiopharmaceuticals into basic categories, either oral
17 I-131 or --

18 COURT REPORTER: Excuse me, this is the court
19 reporter? Who is speaking, please?

20 DR. HOWE: This is Doctor Howe.

21 COURT REPORTER: What is your first name?

22 DR. HOWE: Donna-Beth.

23 COURT REPORTER: Thank you.

24 DR. HOWE: So the idea was to break it into
25 major groups, so that one group would be the oral

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 administration of I-131. And there would be two groups
2 of that, either less than 33 millicuries or greater than
3 33 millicuries.

4 Then the next category was for all
5 radiopharmaceuticals that are used primarily for their
6 photon or electron emissions.

7 So each time you got a new radionuclide,
8 you would look and see what it was being primarily used
9 for. So you would not be making a judgment on every
10 individual new radiopharmaceutical or radionuclide, as
11 long as it fit into the category. And the fourth
12 category was that it was being used primarily for its
13 alpha emissions. And so if something is primarily used
14 for its alpha emissions, it would go into the fourth
15 category.

16 Now, if there were some other type of
17 radionuclide that's not used primarily for its electron,
18 photon, or alpha, then that would go into the statement
19 of consideration we're talking about, that we would
20 review independently.

21 So that was the intent. So the intent is
22 not to look at each individual radionuclide and make
23 regulations for it, but just to see if it fits into one
24 of those four categories.

25 And only if it didn't fit into one of those

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 four categories, would we be making an independent
2 evaluation. Does that help clarify things?

3 MEMBER ZANZONICO: It does, thanks. Another
4 question though. So for example, would an authorized user
5 be authorized to use the individual classes of
6 radiopharmaceuticals?

7 So for example, they could be authorized
8 to use I-131 photon emitted, beta emitted, but
9 conceivably not alpha emitters.

10 DR. HOWE: That's correct. If they did not
11 have clinical experience with the alpha emitters, then
12 they would need the clinical experience with an alpha
13 emitter. And then that would be added to their category.

14 MEMBER ZANZONICO: That's where I think my
15 objection would lie. If an authorized user had the
16 necessary training and experience to use, for example,
17 I-131, or a beta emitter therapeutically, that should
18 suffice to allow them to use the alpha emitters
19 therapeutically, whether or not they had specific
20 experience with an alpha emitter.

21 This is the issue that arose, of course,
22 in connection with the radium dichloride. And so I
23 understand it's not radionuclide by radionuclide, or
24 radiopharmaceutical by radiopharmaceutical, but it is
25 type of emitter by type of emitter authorization.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 And my personal feeling is that that's
2 excessive. I don't know what the feelings of other members
3 of the ACMUI may be.

4 VICE CHAIRMAN THOMADSEN: This is Bruce
5 Thomadsen. And as I recall, our discussion at the ACMUI
6 meeting that was, indeed, the consensus of the group.

7 MEMBER ZANZONICO: Yes. That's my
8 recollection as well. Thank you for confirming that.
9 So I think our --

10 MEMBER LANGHORST: Pat?

11 MEMBER ZANZONICO: Yes.

12 MEMBER LANGHORST: This is Sue Langhorst.
13 May I speak?

14 MEMBER ZANZONICO: Please.

15 MEMBER LANGHORST: One of the confusing
16 factors of adding a parental alpha emitter, there'll be
17 a lot of licensees who don't have that approval to use
18 that type of radiopharmaceutical.

19 So it basically negates being able to get
20 training and experience under 390. And if NRC insists
21 on having all these separate sub-categories, I would
22 recommend that the 390 be done away with, and you keep
23 only the 392, 394, 396, and then add a 398, I guess, for
24 the alpha emitters.

25 Because it gets so confusing as to who's

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 been trained on what. And I agree with Pat. If you know
2 how to administer parental radiopharmaceuticals, alpha
3 versus beta has very little difference.

4 And I don't agree with having the separate
5 Item D in that category for alpha emitters. It makes no
6 sense to me. Thank you.

7 MEMBER ZANZONICO: Thank you.

8 CHAIRMAN MALMUD: So, Pat, what do you
9 recommend at this point?

10 MEMBER ZANZONICO: Let me see if I can
11 formulate this in terms of a votable recommendation.

12 MEMBER SULEIMAN: Well, this is Orhan
13 Suleiman. Can I say something?

14 MEMBER ZANZONICO: Please.

15 MEMBER SULEIMAN: As I recall, I disagreed
16 with the majority at that meeting, because the chemical
17 form of the radio-labeled drug may cause it to behave
18 very differently.

19 And where the radioactivity winds up may
20 cause it to behave very differently. And so whether this
21 is an NRC regulatory requirement, or this is just prudent
22 practice of medicine where the physician has the
23 appropriate privileges to do something, I really have
24 a bad case for lumping everything into simple categories.

25 Because as we're starting to see, the more

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 complicated procedures you have, not only with all sorts
2 of complex therapies, when you start to get into the
3 potential armamentarium for radio-labeled drugs, I don't
4 think you can micro-regulate.

5 But at the same time, I don't think
6 exempting and allowing everybody in the group to have
7 the authority to use all sorts of different radio-labeled
8 drugs is good.

9 Take it away from the Research Institute.

10 Take it away from the Memorial Sloan Kettering, or any
11 of the other places where most of you work. And go out
12 into the hinterland where you've got some users who never
13 show up at these meetings, who really just want to
14 practice medicine, and they're authorized to use a
15 certain class of radioactive drugs.

16 And along comes something that's very
17 similar. And you're going to allow them the authority
18 to start using it when they may, in fact, not have the
19 necessary training. So that's my thinking.

20 How do you protect against that? I'd like
21 to hear from our physician members. How would you ensure
22 that a physician, a nuclear medicine doctor, or a therapy
23 physician at some community hospital who's authorized
24 to use one of these other products, gets something new,
25 and how do you assure that he's got the appropriate

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 training?

2 MEMBER LANGHORST: Sue Langhorst. I know I'm
3 not a physician, but can I take a shot?

4 CHAIRMAN MALMUD: Please do, Doctor
5 Langhorst.

6 MEMBER LANGHORST: Thank you. Orhan, there's
7 a difference between training and experience
8 requirements to become an authorized user and then the
9 license to use certain radioactive materials, and the
10 specific training that a licensee and their authorized
11 users need to have in order to utilize a new
12 radiopharmaceutical.

13 So I think what we're talking about here
14 is what is the base training and experience an authorized
15 user needs to have in order to work with the normal
16 radiopharmaceuticals, and then have enough depth of
17 knowledge that then they can apply with additional vendor
18 training on new radiopharmaceuticals, the specific
19 procedures that have to be in place, both radiation safety
20 and patient safety-wise, in order to administer these
21 new forms of radiopharmaceuticals.

22 MEMBER SULEIMAN: Orhan Suleiman. Well, if
23 that's how it plays out, that's great. But how do you
24 ensure that these individuals will exercise the proper,
25 and again, the proper professional judgment to say I

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 really need training to use this modality.

2 MEMBER ZANZONICO: And this is Pat Zanzonico.

3 Your point is well taken. But my feeling is that parsing
4 radiopharmaceuticals by the type of emission doesn't
5 address that issue.

6 There's always going to be an issue of
7 practitioner competency with any new
8 radiopharmaceutical, or in medical oncology any new drug,
9 or in surgery a new surgical procedure.

10 But in the context of clinical use of
11 radioactive materials, my point, as I said, is that
12 parsing authorization based on type of emission still
13 doesn't address that.

14 You can have very diverse beta emitters,
15 or beta emitting radiopharmaceuticals for therapy, and
16 an AU can be as competent, or incompetent, in using these
17 very different beta emitting radiopharmaceuticals, as
18 using a beta emitter versus an alpha emitter.

19 So it's not that the issue of a learning
20 curve and competency in using different agents is not
21 a real one. It's that parsing them according to radiation
22 emissions doesn't address that issue. It's an
23 artificial regulatory manipulation that really doesn't
24 serve any purpose.

25 MEMBER MATTMULLER: Dr. Malmud, this is Steve

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Mattmuller, if I may.

2 CHAIRMAN MALMUD: Yes, Steve.

3 MEMBER MATTMULLER: First of all, I'd like
4 to agree with Orhan one important point, that I certainly
5 agree that the radiopharmaceutical chemical composition
6 is a far more challenging aspect for physicians getting
7 experience with these therapeutic radiopharmaceuticals,
8 in that the I-131 antibody affects are, Tositumomab is
9 far more challenging to use safely in a patient then,
10 say, a single dose of even radium-226 alpha radon.

11 The type of radioactive emission is really
12 inconsequential. It's the type of radiopharmaceutical
13 that can present a much greater challenge to being used
14 safely.

15 That said, I think we have to realize the
16 limitations of the NRC's regulatory reach, in that they
17 can only regulate per type of radioactive emission,
18 whether we want to go with what they suggested in
19 separating them out, or keeping them all together, as
20 Pat had suggested and Sue had suggested. And I would
21 agree with that concept also.

22 And then just to address Orhan's other
23 concern, actually the FDA, in the introduction of new
24 complex radiopharmaceuticals, it does have a training
25 program for a new user to go through, and prepare to do

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the calculations necessary for planning the treatment.

2 And these calculations all have to be
3 reviewed and approved before they can attain an
4 independent status of using it (telephonic
5 interference). So there is some training in place for
6 the more complex radiopharmaceuticals right now. Thank
7 you.

8 CHAIRMAN MALMUD: Thank you. We're back
9 to the issue, Dr. Zanzonico.

10 MEMBER ZANZONICO: Well, again, I don't think
11 there's disagreement that new or additional training for
12 new and potentially different and more complex
13 radiopharmaceuticals is appropriate.

14 I think where the sub-committee and the
15 ACMUI disagree with the NRC is that basing the training
16 and experience requirements on radiation emissions
17 doesn't address that, and really doesn't serve the public
18 or patients.

19 So unless there was additional comments from
20 the sub-committee or the ACMUI, or the NRC staff, I would
21 offer the following recommendation for a vote, first by
22 the sub-committee, then the committee as a whole.

23 And that is, and it's basically the last
24 sentence of Item 2-D, namely "Pracitioners who have the
25 requisite training and experience to safely and

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 effectively utilize any emitter diagnostically, and/or
2 therapeutically, have the training and experience to
3 utilize all of them. And authorization should not be
4 emission specific."

5 So what I'm asking for then, is approval
6 by the sub-committee, and then the committee as a whole,
7 to submit that recommendation to the NRC.

8 CHAIRMAN MALMUD: So you're putting the
9 motion before the sub-committee.

10 MEMBER ZANZONICO: Correct.

11 CHAIRMAN MALMUD: And you're going to poll
12 the sub-committee. All right, polling the sub-committee,
13 all in favor of this motion --

14 MEMBER WEIL: Dr. Malmud, this is --

15 CHAIRMAN MALMUD: Who's speaking please?

16 MEMBER WEIL: This is Laura Weil.

17 CHAIRMAN MALMUD: Yes?

18 MEMBER WEIL: Before we actually vote, could
19 I ask NRC staff to respond to Doctor Zanzonico's last
20 comment, and justify why they feel it might be inadequate?

21 CHAIRMAN MALMUD: Certainly you can ask.
22 NRC staff, who wishes to respond? Doctor Howe?

23 DR. HOWE: Getting off mute. When we look
24 at the radiation safety issues that are associated with
25 different radionuclides, we believe that the radiation

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 safety that's involved with photons, and then with beta
2 particles, or with alpha, are very different.

3 With radium-223 we were able to look at how
4 you measured it. And you measured it basically using the
5 photons. And so there wasn't a difference as to how you
6 could detect contamination, how you could measure what
7 you believe to be the activity of things.

8 You could use the same equipment that you
9 were using automatically already. But we do believe that
10 there's a difference in how beta particles interact, and
11 that since most nuclear medicine positions are primarily
12 photon, that there is a need for additional training for
13 some of these new emitters coming down. So that's our
14 basic reasoning. Thank you.

15 CHAIRMAN MALMUD: Does that answer your
16 question?

17 MEMBER WEIL: It does. It does and I have
18 to say that I agree with NRC staff on this.

19 MEMBER LANGHORST: Dr. Malmud, this is Sue
20 Langhorst.

21 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

22 MEMBER LANGHORST: I would like to get a
23 clarification from Dr. Zanzonico. Pat, are you saying
24 that the NRC should do away with the different levels
25 of I-131 therapy and diagnostics?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MEMBER ZANZONICO: No, Sue. Because I think
2 that there is a fundamental distinction between whether
3 one is using radioactivity diagnostically or
4 therapeutically.

5 If one is using it therapeutically, the
6 authorized user has a responsibility to medically manage
7 a patient who may suffer acute or deterministic effects
8 as a result, and has to have the training and experience
9 to do that properly.

10 If one is strictly using them
11 diagnostically, those classes of effects are
12 inapplicable. So I mean I think there is a fundamental
13 distinction between, or among, or between therapeutic
14 and diagnostic applications and therefore in relation
15 to administered activities.

16 But I think all authorized users, and who
17 use radioactivity clinically, have training and
18 experience in radiation physics, in radiation detection
19 and instrumentation and so forth. And understand the
20 capabilities and limitations of different instruments
21 in detecting different types of radiations and so forth.

22 So it's not to say that there aren't valid
23 distinctions and valid reasons for different types of
24 required training and experience among different
25 applications of radiopharmaceuticals or radioactivity

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 clinically, but that basing that distinction strictly
2 on admissions is not a valid one.

3 MEMBER LANGHORST: Okay, this is Sue
4 Langhorst again. I think the first part of 390 is I-131
5 sodium iodide less than 33 millicuries. And please for
6 give me for that old unit.

7 The other one is I-131 sodium iodide greater
8 than that. And I think those two, first one tends more
9 towards diagnostic use. Second one is definitely therapy.

10 I think what you're proposing, Pat, and
11 please forgive me for trying to put words in your mouth,
12 but I think is that the parenteral-administration, as
13 opposed to those first which are oral, the parenteral
14 you're saying don't have two separate categories for
15 that, have it be one category that includes all the photon
16 betas and alpha emitters?

17 MEMBER ZANZONICO: Yes, that's basically
18 correct.

19 MEMBER LANGHORST: Okay, I agree with that.
20 Thank you.

21 CHAIRMAN MALMUD: Just a minor correction.
22 The lower doses of I-131 below grade are also therapeutic
23 therefore hyperthyroidism versus the ones that are 100
24 millicuries or more which tend, or 50 millicuries or more
25 which tend to be for thyroid cancer. Or for thyroid

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 cancer.

2 MEMBER LANGHORST: Thanks for correcting me
3 Dr. Malmud, this is --

4 CHAIRMAN MALMUD: Okay, I'm sorry. But you
5 are also correct in that there are lower doses of I-131
6 in the order of 3 millicuries, which is still used in
7 remote locations where I-123 is not available for
8 diagnostic purposes. You are correct in that.

9 At any rate, getting back to the subject.
10 So Dr. Zanzonico, the ball is in your court.

11 MEMBER ZANZONICO: Well I would still, I mean
12 I appreciate the comments and the rationale offered by
13 the NRC staff, but I'm unconvinced at this point and would
14 still offer my recommendation for a vote. And I can
15 repeat it if you like?

16 CHAIRMAN MALMUD: Please repeat it.

17 MEMBER ZANZONICO: Okay. The recommendation
18 would be, or the vote would be to recommend to the NRC
19 the following:

20 "Practitioners who direct the training and
21 experience to safely and effectively utilize any
22 radiopharmaceutical, diagnostically and
23 therapeutically, have the training and experience to
24 utilize all of them and authorization therefore should
25 not be emission specific."

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: That is the motion.

2 VICE CHAIRMAN THOMADSEN: Okay, this is Bruce
3 Thomadsen. If I could propose an amendment? Instead of
4 all of them, any of them.

5 MEMBER ZANZONICO: Okay, agreed.

6 CHAIRMAN MALMUD: Any other amendments to
7 this motion which is being put before the subcommittee?

8 MEMBER LANGHORST: Well we have, this is Sue
9 Langhorst, so we have a chance to ask more questions?

10 CHAIRMAN MALMUD: Absolutely.

11 MEMBER LANGHORST: Can I now?

12 CHAIRMAN MALMUD: Yes you may.

13 MEMBER LANGHORST: Pat, I believe what you're
14 proposing here encompasses all of 190, 290 and 390? And
15 so I don't think I can agree with this.

16 And that's why I was trying to clarifying,
17 you're only talking 390 and are you only talking C and
18 D items or do you mean NRC should do away with 190, 290
19 and 390?

20 MEMBER ZANZONICO: I have to confess to you,
21 I'm just not as familiar off the top of my head with the
22 Sections of the Regs as you are. The gist of what I'm
23 trying to propose, and perhaps you can formulate it in
24 a much better way, but the gist of what I'm trying to
25 propose is eliminating the language, or the sections in

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 the proposed rule, which would require separate training
2 and experience based on type of emission, of radiation
3 emission.

4 MEMBER LANGHORST: And this is Sue Langhorst
5 again. So you mean between the beta emitting therapy
6 radiopharmaceuticals, beta and proton emitting versus
7 alpha emitting? Is that the --

8 MEMBER ZANZONICO: Correct.

9 MEMBER LANGHORST: Okay, so I would agree
10 with your point if that's what you're limiting it to.

11 But the wording you're using is all and any.

12 MEMBER ZANZONICO: Yes, understood. So --

13 MEMBER LANGHORST: I would recommend that
14 the motion might be that ACMUI recommends that alpha
15 emitter, parenteral-administered alpha emitting
16 radiopharmaceuticals not be separately called out for
17 training and experience, that instead the training and
18 experience should be limited to
19 parenteral-administration of radiopharmaceuticals?

20 MS. BHALLA: Dr. Malmud?

21 CHAIRMAN MALMUD: Yes.

22 MS. BHALLA: Yes, this is Neelam Bhalla
23 again, from NRC.

24 CHAIRMAN MALMUD: Yes.

25 MS. BHALLA: So for clarification, I think

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 it's important to then defer to Section 35-C-96, because
2 that's the section that pertains to the
3 parenteral-administration of radiopharmaceuticals.

4 So that would eliminate any confusion about
5 going back to 190, 290, et cetera because those sections
6 are not included in the -- again I'll talk about the user
7 need memo where the request came that right now we have,
8 under the 35-C-96, categorization of certain beta
9 emitters and then gammas up to a certain energy.

10 But there was no, I think that question came
11 up, what about alpha emitters? So the staff expressed
12 a need to create a separate category for that modality
13 and that's why this was open. So when you make your report,
14 please refer to Section 35-C-96 because that's what's
15 open to amendment.

16 CHAIRMAN MALMUD: Thank you for that.

17 DR. HOWE: Dr. Malmud?

18 CHAIRMAN MALMUD: Yes.

19 DR. HOWE: Dr. Malmud, this is Dr. Howe.
20 Actually 390 and 396 are both open because 396 pertains
21 only to the radiation oncologist, where 390 applies to
22 the nuclear medicine physicians.

23 CHAIRMAN MALMUD: Thank you for clarifying
24 that, Dr. Howe.

25 MEMBER LANGHORST: This is Sue Langhorst.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 Dr. Howe, I disagree with that. 390 refers to any
2 physician that meets that requirement, be they radiation
3 oncologist or nuclear medicine.

4 My radiation oncologists are approved under
5 the 390, so I don't think you can clarify it in that
6 simplistic of terms.

7 DR. HOWE: Well the, this is Dr. Howe again.

8 The original intent for 396 was to allow radiation
9 oncologists that have authorized users status as
10 radiation oncologist, to use parenteral treatment
11 without having to go through the 200 hours and the other
12 requirements in 390.

13 Now I understand some of the board
14 certifications are covering both now, but if you look
15 carefully at 396, the criteria for using 396 is that your
16 are either recognized under 35-400, which is
17 brachytherapy, or in 360, which is the remote
18 afterloader, the teletherapy and the gamma
19 stereotactics. So there is a distinction there, although
20 it's getting a little fuzzier.

21 MEMBER LANGHORST: This is Sue Langhorst.
22 My point is, is that radiation oncologist also practice
23 under 300. I mean not just that one section, but all
24 of 390.

25 MEMBER WELSH: This is Jim Welsh. I fully

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 agree with what Dr. Langhorst has just said. It's part
2 of the board requirements now.

3 MEMBER LANGHORST: Dr. Malmud, this is Sue
4 Langhorst again?

5 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

6 MEMBER LANGHORST: I would like to suggest
7 that maybe the subcommittee work on the wording for this
8 section a little bit in this week between our
9 teleconferences and bring forward some new language on
10 it?

11 MEMBER ZANZONICO: This is Pat Zanzonico.
12 I agree completely. I think we're in agreement on the
13 sense of what we want to express, but it will require
14 some additional discussion to formulate it properly.

15 CHAIRMAN MALMUD: Okay, that's a decision
16 which the subcommittee chair can deal with. Dr.
17 Zanzonico?

18 MEMBER ZANZONICO: Absolutely. And so we
19 would just defer this item, Item 2D to our offline
20 discussion and then pick it up again at our next
21 teleconference.

22 CHAIRMAN MALMUD: Or the next meeting.

23 MEMBER ZANZONICO: Or the next meeting.

24 CHAIRMAN MALMUD: Thank you. Is that
25 acceptable to the staff?

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MS. BHALLA: Dr. Malmud?

2 CHAIRMAN MALMUD: Yes.

3 MS. BHALLA: We would really appreciate it
4 if it's done at the next teleconference which is scheduled
5 for next week, I suppose, to meet our schedule for the
6 rule to be taken to the commission.

7 CHAIRMAN MALMUD: Thank you. Can that date
8 be met Dr. Zanzonico?

9 MEMBER ZANZONICO: Absolutely.

10 CHAIRMAN MALMUD: Okay, you're wish is
11 subcommittee's command. Thank you. Dr. Zanzonico?

12 MEMBER ZANZONICO: Before continuing, the
13 question I have is, what the schedule is in terms of the
14 next teleconference?

15 I'm wondering at this point, since we're
16 approaching the end of the allotted time for today's
17 teleconference, if it might be more logical and more
18 productive to resume our discussion, first with this last
19 point and then go on to Item 3 and the remaining items
20 at that time as opposed to beginning a discussion of these
21 additional items at this point?

22 CHAIRMAN MALMUD: I think that's a
23 constructive suggestion. The Committee maybe facing
24 fatigue since we're approaching three hours. Is that
25 acceptable to the members of the NRC staff as well as

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 to our Committee members?

2 MS. BHALLA: Dr. Malmud, this is Neelam
3 Bhalla. Very quickly I wanted to bring one clarification
4 so that when we meet next time maybe the subcommittee
5 can take a look at that before we meet?

6 CHAIRMAN MALMUD: You want to --

7 MS. BHALLA: And that should not --

8 CHAIRMAN MALMUD: I beg your pardon?

9 MS. BHALLA: I said that should not take
10 long, it's one clarification I want to make and so that
11 when we meet next time subcommittee would have had time
12 to look at that.

13 CHAIRMAN MALMUD: All right, Dr. Zanzonico,
14 is that okay?

15 MEMBER ZANZONICO: Absolutely, no please.

16 CHAIRMAN MALMUD: Go ahead then.

17 MS. HOLIDAY: I just wanted to interject
18 really quick, this is Sophie. I believe you asked for
19 what our schedule is like and so we do have a backup
20 teleconference scheduled for next week on the 12th at
21 the same time, from 2:00 to 5:00 p.m.

22 The ACMUI was given the draft, the proposed
23 draft FRN December 21st. So our 90-day deadline to receive
24 your comments in the form of a final report would be March
25 21st.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 So if at all possible, we would like to
2 resolve all comments and have approval or a consensus
3 on that subcommittee report by the end of next meeting?

4 MEMBER ZANZONICO: Ms. Sophie, that's our
5 intent, absolutely.

6 MS. HOLIDAY: Great, thank you.

7 CHAIRMAN MALMUD: We shall endeavor to do
8 so Sophie.

9 MS. HOLIDAY: Thank you, Dr. Malmud.

10 CHAIRMAN MALMUD: Dr. Zanzonico and Bhalla?

11 MEMBER ZANZONICO: Well I just wanted to hear
12 this comment related to Item 3A?

13 CHAIRMAN MALMUD: Yes.

14 DR. BHALLA: Yes. So in Item 3A, which is
15 about extending grandfathering to certain certified
16 individuals, which is the Ritenour Petition.

17 I would just bring the, it seems like when
18 you read this paragraph, especially the last line it says,
19 wouldn't they already be named on our license? This is
20 with regard to those qualified individuals.

21 It seems like it's a question and I just
22 wanted to make the clarification that the whole of the
23 Ritenour Petition was based on the fact that there were
24 certain individuals. Namely, the petitioner said, the
25 RSOs and the physicists who were not named on the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 licensed, because 35-57 starts with these individuals
2 who were certified on an NRC license.

3 So the petition came, we said that well there
4 were people who were qualified but they were not named
5 on a license and therefore here NRC, do something about
6 it for these individuals. So I just wanted to do that
7 clarification right now, that the entire petition is
8 based on the fact these people were not licensed, were
9 not named on a license and therefore they got kind of
10 left behind or they were not grandfathered.

11 So with that clarification, maybe the
12 subcommittee would rethink as to why the importance laws
13 of that particular date be October 2005. Because that's
14 when the old Subpart J went away and these people who
15 were not named on a license, now they needed to, or right
16 now they need to meet the new requirement.

17 And therefore what we want to or how we want
18 to correct that, is to bring back all those rules. And
19 you would have seen that in the proposal. We literally
20 brought the old rules back into the Regs.

21 We didn't want to refer them to, that go
22 back to 2002 or to 2005 and go look at all the rules.
23 So I just wanted to bring that to the attention of the
24 subcommittee that the date is important and that, yes
25 indeed, these people were not listed on the license.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: Thank you and --

2 MEMBER ZANZONICO: Thank you.

3 CHAIRMAN MALMUD: -- what's the proposed
4 resolution to the issue?

5 MEMBER LANGHORST: Dr. Malmud, this is Sue
6 Langhorst.

7 CHAIRMAN MALMUD: Yes Dr. Langhorst.

8 MEMBER LANGHORST: Neelam, thank you very
9 much for your clarification on that because I don't think
10 that the language in the draft proposed rule right now
11 makes that clear. And that's what we were trying to get
12 across in this point.

13 And so we will be a little more, Pat, if
14 you allow me to say this, we'll be a little more careful
15 in pointing out where we think that is not made clear
16 in the draft proposed rule that you have before us.

17 MEMBER ZANZONICO: Absolutely.

18 MS. BHALLA: And this is Neelam again. And
19 we appreciate that and we would make that clarification
20 that these were the people who were not named on the
21 license.

22 CHAIRMAN MALMUD: Thank you.

23 MEMBER ZANZONICO: That's helpful, I think
24 it will, that this will expedite the discussion of this
25 item on the next teleconference.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 MS. BHALLA: Correct.

2 CHAIRMAN MALMUD: Thank you.

3 MS. BHALLA: Thanks.

4 CHAIRMAN MALMUD: It's about 5:05 now in
5 eastern standard time. So unless there's objection, we
6 will call an end to the meeting today, pick it up at the
7 next session which is on the March the 12th at 2:00 to
8 5:00 p.m.

9 Hopefully complete all the (telephonic
10 interference) that time so that we could meet the
11 deadline, which is March 21st. Is that agreeable with
12 everyone?

13 MEMBER ZANZONICO: Yes.

14 CHAIRMAN MALMUD: Is there anything of any
15 urgency that anyone feels must be brought today up at
16 this time?

17 MS. HOLIDAY: Dr. Malmud, this is Sophie.

18 CHAIRMAN MALMUD: Yes, Sophie.

19 MS. HOLIDAY: I would like to make the
20 announcement for members of the public, if you wish to
21 participate, or if wish to call in to listen to
22 teleconference meetings on next Tuesday, please send me
23 an email and I will provide you with the bridgeline
24 information, it would be different from the one that was
25 used today.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

1 CHAIRMAN MALMUD: Thank you. And I know that
2 we'll receive an email from you with regard to the
3 members' bridgeline?

4 MS. HOLIDAY: Yes, sir.

5 CHAIRMAN MALMUD: Thank you. Any other issues
6 to be brought up today? If not I want to thank everyone
7 for participating in this call today, particular Dr.
8 Zanzonico and the members of the subcommittee who've done
9 an extraordinary amount of work since we last spoke.

10 I've been following all the progress and
11 discussion via the emails. And I want to thank you all
12 again and we'll look forward to meeting again next week.

13 MEMBER ZANZONICO: Very good, thank you.

14 CHAIRMAN MALMUD: Thank you all.

15 MEMBER ZANZONICO: Bye, bye then.

16 CHAIRMAN MALMUD: Is there comment from NRC
17 staff?

18 MR. EINBERG: This is Chris Einberg. On
19 behalf of the NRC staff we want to thank the ACMUI and
20 the subcommittee for all this very hard work. I know it's
21 been quite a bit to review and so we greatly appreciate
22 all your input.

23 CHAIRMAN MALMUD: Thank you all.

24 MEMBER ZANZONICO: Okay, thank you bye, bye.

25 CHAIRMAN MALMUD: Bye.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com

MEMBER LANGHORST: Bye.

(Whereupon, the hearing in the
above-mentioned matter was adjourned at 4:53 p.m.)

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS

1323 RHODE ISLAND AVE., N.W.

WASHINGTON, D.C. 20005-3701

(202) 234-4433

www.nealrgross.com