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 1-111

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

1 PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist
2
3 ACMUI MEMBERS NOT PRESENT:
4 JOHN SUH, M.D., Radiation Oncologist
5
6 NRC HEADQUARTERS STAFF PRESENT:
7 PAMELA HENDERSON, Deputy Director, Division of
8 Materials Safety and State Agreements
9 CHRIS EINBERG, Designated Federal Officer
10 ASHLEY COCKERHAM, Alternate Designate Federal
11 Officer, ACMUI Coordinator
12 SOPHIE HOLIDAY, Alternate ACMUI Coordinator
13 NEELAM BHALLA, FSME/DILR/RPMB
14 SUSAN CHIDAKEL, OGC/GCLR/RMR
15 SAID DAIBES, Ph.D., FSME/DMSSA/RMSB
16 JAMES DANNA, FSME/DILR/RB-B
17 TREMAINE DONNELL, OIS/IRSD/ISB/ICT
18 SANDRA GABRIEL, Ph.D., FSME/DMSSA/RMSB
19 DONNA-BETH HOWE, Ph.D., FSME/DMSSA/RMSB
20 ED LOHR, FSME/DILR/RPMB
21 DEBBIE PISKURA, FSME/DMSSA/RMSB
22 GRETCHEN RIVERA-CAPELLA, FSME/DMSSA/RMSB
23 SANDRA TALLEY, FSME/DWMEP
24 RONALD ZELAC, Ph.D., FSME/DMSSA/RMSB
25

1 NRC REGIONAL STAFF PRESENT:

2 MARYANN ABOGUNDE, R-I

3 HECTOR BERMUDEZ, R-II

4 COLLEEN CASEY, R-III

5 JACKIE COOK, R-IV

6 SARA FORSTER, R-III

7 MICHELLE HAMMOND, R-IV

8 PENNY LANZISERA, R-I

9 DENNIS O'DOWD, R-III

10 BRYAN PARKER, R-III

11 PATTY PELKE, R-III

12 MICHELLE SIMMONS, R-IV

13 JACK WHITTEN, R-IV

14

15 PUBLIC PARTICIPANTS PRESENT:

16 SUE BUNNING, Society of Nuclear Medicine and

17 Molecular Imaging

18 WILLIAM DAVIDSON, University of Pennsylvania

19 DAWN EDGERTON, Council for Certification in

20 Cardiovascular Imaging

21 LYNNE FAIROBENT, AAPM

22 THOMAS HUSTON, Department of Veterans Affairs,

23 National Health Physics Program

24 KAREN LANGLEY, University of Utah

25 RALPH LIETO, St. Joseph Mercy Hospital

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

CONTENTS

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

2 2:03:02 p.m.

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

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

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

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

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

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

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

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

1 and regulations of the Federal Advisory Committee Act and
2 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 or
9 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.

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

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?

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 IV.

7 MR. WHITTEN: Jack Whitten.

8 MS. HAMMOND: Michelle Hammond.

9 MS. SIMMONS: Michelle Simmons.

10 MR. EINBERG: Okay. And now anybody else from

11 Headquarters who is calling in remotely?

12 DR. HOWE: Donna-Beth Howe.

13 DR. GABRIEL: Sandy Gabriel.

14 DR. ZELAC: Ron Zelac.

15 MS. COCKERHAM: Ashley Cockerham.

16 MR. EINBERG: Okay. And we also have Jim

17 Danna on the phone. We have the bridge line available and

18 that phone number is 888-864-0940. The pass code to

19 access the bridge line is 35793#.

20 I now ask the members of the public who are

21 present to identify themselves.

22 MS. FAIROBENT: Lynne Fairobent, AAPM.

23 MR. EINBERG: Okay.

24 MS. TOMLINSON: Cindy Tomlinson, ASTRO.

25 MS. BUNNING: Sue Bunning, SNMMI.

1 MR. HUSTON: Tom Huston, Department of
2 Veterans Affairs.
3 MS. ROMANELLI: Gloria Romanelli, ACR.
4 MR. PETERS: Mike Peters, American College
5 of Radiology.
6 MR. STEPHENS: Mike Stephens, Florida.
7 MS. LANGLEY: Karen Langley, University of
8 Utah.
9 MR. McKINLEY: Andrew McKinley with ASNC.
10 MS. EDGERTON: Dawn Edgerton, CBNC/CCCVI.
11 MR. EINBERG: Okay.
12 MR. SHEETZ: Mike Sheetz, University of
13 Pittsburgh.
14 MR. RODGERS: Joe Rodgers, Theragenics
15 Corporation.
16 MR. EINBERG: Okay, we're going to proceed
17 then.
18 This is a Category I public meeting. This
19 is an open public observatory meeting that is
20 non-participatory. Members of the public may listen to
21 the meeting. The draft proposed expanded Part 35 rule is
22 considered pre-decisional and has not been transmitted
23 to the NRC Commission for a vote. The rule is anticipated
24 to be sent to the Commission in the later summer of 2013.
25 After Commission approval, the rule will be

1 published in the Federal Register and members of the
2 public will be given a 90-day comment period pending
3 Commission approval versus the typical 75-day comment
4 period.
5 While this meeting is a meeting of the
6 ACMUI, NRC Staff is available to answer questions from
7 the ACMUI members.
8 At this point, I would like to turn the
9 meeting over to Dr. Malmud.
10 CHAIRMAN MALMUD: Thank you. At this point,
11 as Chairman I will turn the Committee over to the
12 Committee Chairman, the Subcommittee Chairman, Dr.
13 Zanzonico, who has an extensive report for us. Dr.
14 Zanzonico.
15 MEMBER ZANZONICO: Yes. Thank you, Dr.
16 Malmud. Hello, everyone.
17 I'm Pat Zanzonico from Memorial
18 Sloane-Kettering Cancer Center in New York City, and I
19 had the pleasure of serving as the chairperson of the
20 ACMUI Subcommittee on the proposed rule.
21 Our report has been made publicly available
22 through the NRC, and presumably members of the public as
23 well as of the NRC and, of course, members of the ACMUI
24 have had an opportunity to look at it. So, I think I will
25 just summarize some of the major points and then we can

1 move on to a discussion.

2 I should point out that to expedite our

3 review, the review of the Subcommittee, we inserted line

4 numbers into the proposed rule, and many of our comments

5 reference both the page and line numbers, especially with

6 respect to specific comments. And we divided our report

7 into two major sections, general comments which

8 basically deal with major regulatory issues in a general

9 way, significant specific comments, again referenced by

10 line and page numbers, and minor specific comments,

11 really editorial comments likewise referenced by page

12 and line number.

13 And the real key component of our report,

14 of course, are the general comments. And we had seven such

15 areas that we identified in the draft -- in the proposed

16 rule upon which we commented. And I'd also like to thank

17 all my fellow members of the Subcommittee for their time,

18 effort, and due diligence. I mean, everyone really put

19 in a lot of time, and effort, and thought into submitting

20 comments and reviewing the proposed rule. And in advance

21 of this meeting there was a lot of give and take, very

22 collegial, but give and take, nonetheless, among the

23 members of the Subcommittee.

24 So, just to go through the general comments.

25 The first issue, and I think really the most contentious,

1 for lack of a better term, was the proposed definition
2 of a medical event for permanent implant brachytherapy.
3 And the key features of the new proposed definition which
4 was based on the recommendations of a Subcommittee of the
5 ACMUI, and subsequently endorsed by the entire
6 Committee, basically expresses or defines a medical
7 event in permanent implant brachytherapy largely in
8 terms of source strength in the proposed rule rather than
9 in terms of radiation absorbed dose. And I think that's
10 the key distinction.
11 Now, it was pointed out by at least one
12 member of our Subcommittee, and we included a sort of
13 historical review of the -- or the evolution of the ME
14 definition in the regulatory literature. And at least one
15 member of the Subcommittee pointed out that really the
16 proposed rule for an ME for permanent implant
17 brachytherapy is actually not fundamentally different in
18 our opinion from the existing definition. So, in that it
19 allows a definition of an ME in terms of source strength
20 or activity rather than dose, or in addition to dose.
21 So, one suggestion was made that until the
22 proposed rule is finalized and adopted it might be
23 prudent to include activity-based MEs until that rule is
24 adopted, because it is, in fact -- such a definition is,
25 in fact, consistent with the existing regulation, the

1 regulatory language in our opinion.

2 Another issue that was raised by the

3 Subcommittee was concern about the complexity or

4 perceived complexity of the proposed ME definition for

5 permanent implant brachytherapy. And this was

6 specifically related to the provision in which an ME

7 -- one of -- or two of the criteria for an ME in permanent

8 implant brachytherapy was a dose to five contiguous cubic

9 centimeters of normal tissue whether it was within the

10 treatment site or outside of the treatment site. So,

11 additional criteria in the new ME definition would mean

12 that if the dose to such a five cubic centimeter

13 contiguous volume of normal tissue exceeded the

14 prescribed absorbed dose to the target by more than 20

15 percent, that would meet the criteria for a medical

16 event.

17 So, there was some concern that that might

18 be onerously complex in the field for both users and

19 regulators for inspection. So, one suggestion was made

20 that the NRC solicit from stakeholders some feedback on

21 whether the complexity or perceived complexity of the ME

22 definition in that respect might discourage

23 practitioners from using permanent implant

24 brachytherapy, you know, simply to avoid that

25 complexity. Apparently, in supplemental information

1 Section 4D, there's a provision for soliciting such
2 feedback from stakeholders.
3 Another concern with respect to the ME
4 definition was the compatibility category assigned to
5 the proposed ME definition for permanent implant
6 brachytherapy. And the current designation is as
7 Compatibility Category C, which to our understanding
8 allows Agreement States to retain the dose-based
9 criteria for definition of an ME. And it was explained
10 very eloquently in the proposed rule the rationale for
11 moving from a dose-based to an activity-based criteria;
12 the most important consideration being that the
13 dose-based criteria seemed not to be sensitively and
14 specifically capturing clinically significant medical
15 events, and even certain, for lack of a better term,
16 bookkeeping issues which really had little to no clinical
17 impact were being designated or defined as MEs.
18 So, it seemed that if the designation of
19 Compatibility Category C were allowed to stand, that that
20 confusion or lack of sensitivity and specificity for
21 clinically significant ME's would be perpetuated, so our
22 Subcommittee recommended that this new definition of MEs
23 for permanent implant brachytherapy be designated as
24 Compatibility Category B.
25 We also, thanks to Dr. Welsh, identified a

1 literature reference, a specific reference in support of
2 the five cubic centimeter of contiguous normal tissue
3 criteria for an ME, and we included that reference which
4 is from a working group. We included that reference in
5 our comments.
6 So, I believe those summarize our major
7 concerns with and comments on the proposed definition for
8 an ME for permanent implant brachytherapy. So, I presume
9 we're going to hold discussion until I've gone through
10 the synopsis of the report. Is that correct, Dr. Malmud?
11 CHAIRMAN MALMUD: That would be the most
12 efficient way to handle it, I believe.
13 MEMBER ZANZONICO: Agreed, agreed.
14 Okay. So, in that case then I'll just move
15 on to the second issue we addressed in our report which
16 was the training and experience requirements for
17 authorized users, medical physicists, radiation safety
18 officers, and nuclear pharmacists. And our Subcommittee,
19 and I think the entire ACMUI is unanimously enthusiastic
20 about eliminating the preceptor statement requirement
21 for Board certified individuals. That was just kind of
22 an endorsement of that point that we wanted to emphasize.
23 A second point had to do with the
24 requirement for authorized users on the elution of
25 generators. It appeared that there was -- it's not an

1 additional, an explicit requirement for T&E, for
2 training and experience on elution of generators. And
3 we felt that that training and experience was adequately
4 -- the requirement for that training and experience was
5 adequately covered in the existing training and
6 experience requirements, and that it was unnecessary,
7 and redundant, and so forth to include a separate
8 training and experience requirement on that particular
9 item. As I say, it was felt that the training and
10 experience requirements overall for authorized users
11 implicitly included that particular item; in other
12 words, elution of generators.
13 The other point we had with respect to
14 training and experience requirements had to do with the
15 language that preceptor attestations would use, and we
16 really felt that it was more than a matter of semantics.
17 For example, on page 19 in Section 4B there was language
18 stating that a preceptor should attest that a authorized
19 user, RSO, et cetera, satisfactorily completed the
20 necessary training and experience requirements, and has
21 achieved the level of competency sufficient to function
22 independently in the position for which authorization is
23 sought. And we felt that as worded such an attestation
24 really puts an untenable burden on preceptors in that it
25 requires them to make a subjective judgment as to the

1 professional competency of an individual. And what we
2 felt was actually being sought, and what was more
3 appropriate was somewhat amended language; namely, has
4 satisfactorily fulfilled the training and experience
5 requirements consistent with achieving a level of
6 competency sufficient to function independently in the
7 position for which authorization is sought.
8 And, again, the distinction is subtle, but
9 we think not insignificant between the proposed and this
10 new language in that it eliminates the burden on the
11 preceptor to make a subjective judgment as to
12 professional competency or not. Rather, it simply asks
13 the preceptor to attest that the person seeking
14 authorization had satisfied residency and other
15 requirements of a training program. And we think that's
16 a significant in language. And if you read our report you
17 saw that we -- that that sort of language and the
18 suggested change was made at multiple points throughout
19 the proposed rule and throughout our comments.
20 The final point we had with respect to
21 training and experience requirements was -- had to do
22 with certain elements of Section 35.390. And lines 1503
23 to 1508 in that section states that the current
24 regulation include a broad category for parenteral
25 administration of any other radionuclide. This broad

1 category would be removed as any new parenteral
2 administration of radionuclides not listed in this
3 paragraph would be regulated under 35.1000.
4 "This approach would allow the NRC to review
5 each new proposed radionuclide for parenteral
6 administration and determine the appropriate training
7 and experience for its use."
8 And the reservations we have about that is
9 that it appears it would require each new
10 radiopharmaceutical -- that the training and experience
11 requirements for each new radiopharmaceutical that might
12 be introduced. For example, as we recently saw the
13 radium-223 dichloride issue. And our feeling was that an
14 authorized user who has demonstrated acceptable
15 training, and experience, and so forth for any one
16 category of radiopharmaceuticals such as gamma and beta
17 emitters has demonstrated adequate training and
18 experience for all radiopharmaceuticals, that in terms
19 of radiation physics, radiation safety, radiation
20 biology, and clinical applications, all of these
21 radiopharmaceuticals are much more alike than they are
22 different. And it would just seem to be unnecessarily
23 burdensome and so forth to allow the possibility of
24 radiopharmaceutical by radiopharmaceutical review of
25 credential as new radiopharmaceuticals are introduced.

1 And it sounds like, or at least we infer from the language
2 as proposed that that might be the case.
3 So, that concludes our comments on the training and
4 experience provisions of the proposed rule.
5 The next issue is extending grandfathering
6 to certain certified individuals. And this is -- has come
7 to be known as the Ritenour petition. And the ACMUI had
8 previously recommended that all board-certified
9 individuals, individuals certified by Boards
10 recognized, professional Boards recognized by the NRC
11 should be grandfathered, and that should be independent
12 of the date of the recognition of the Board by the NRC.
13 You know, the ACMUI has argued that the most
14 appropriate group of individuals to judge the
15 professional qualifications of a practitioner are that
16 practitioner's professional peers, namely, the Boards.
17 And that certainly we understand the NRC has a regulatory
18 obligation to review Boards themselves and to decide
19 which Boards are or not acceptable. But we felt that an
20 arbitrary date and time was not reasonable, that once a
21 Board has been recognized and regardless of the date of
22 board-certification of an individual, or the date of
23 recognition of that Board by the NRC, that that
24 board-certification should be de facto evidence for the
25 NRC of that individual's professional qualifications.

1 There was a second point that was raised by
2 our Subcommittee in terms of certain terminology the NRC
3 has used and is using. And terms such as type of use,
4 modality, and category should be explicitly defined in
5 Section 35.2 definitions so that the regulatory meaning
6 of these three terms, in particular, be understood.
7 And, again, a third point, but it's really
8 related to the first point I made, as well, was the --with
9 respect to the Ritenour petition was the impact of the
10 date of recognition of a certifying Board by the NRC. And
11 just to reiterate, the ACMUI has recommended and still
12 recommends that the date of recognition should not impact
13 individuals seeking to be named as an authorized user or
14 other practitioner. Once the Board has been recognized,
15 the date of its recognition is really irrelevant in our
16 opinion.
17 The next general item we addressed and
18 included in the proposed rule is measuring molybdenum
19 contamination for each elution of a molybdenum
20 technetium generator and reporting a failed breakthrough
21 test; that is, a breakthrough test in which the
22 molybdenum concentration was out of tolerance.
23 And it was pointed out, of course, that
24 currently there are two generator systems in routine use
25 in nuclear medicine; of course, the molybdenum-99,

1 technetium-99 generator system, and the strontium-82, or
2 strontium-89, rubidium-89 generator systems for cardiac
3 studies. And as has been pointed out, there are other
4 generator systems like gallium/germanium generator
5 systems that are on the horizon, so we raised the issue
6 of whether these newer generator systems should be
7 included in the proposed rule, or should it somehow be
8 generalized to include all current and future generator
9 systems.
10 The other issue had to do with the NRC
11 regulation in terms of breakthrough, generator
12 breakthrough as it relates to FDA labeling requirements.
13 And at least one of our Subcommittee members felt very
14 strongly that a better way overall of regulating
15 generator breakthrough testing would be to simply defer
16 to the FDA labeling requirements. The FDA will, of
17 course, promulgate labeling requirements for every
18 generator system as it becomes a marketed product, so if
19 the NRC were to defer to the FDA labeling requirements
20 on this point, then it would automatically take care of
21 the NRC regulation for these newer generators as they're
22 introduced into clinical use without the need for a
23 revision of existing rules, and all of the time, and
24 effort, and review that that entails, as well.
25 The NRC argued in the proposed rule and made

1 a number of arguments as to why it felt that was not an
2 optimum way to go, but without going into it on a point
3 by point basis, in our report we address the NRC's
4 arguments on this point; namely, the NRC's rationale as
5 to why their own regulation rather than FDA labeling
6 requirements would be more appropriate. And our
7 conclusion was that we really -- we meaning the
8 Subcommittee did not find those arguments compelling,
9 and really felt that deferring to the FDA labeling
10 requirements would ultimately be a more effective and
11 more expeditious way of dealing with this issue.
12 And, you know, there was also concern about
13 the reporting requirement itself. In the proposed rule,
14 the NRC is basically requiring that licensees submit to
15 at least two notifications, one to the NRC and one to the
16 vendor or manufacturer within 24 hours of the finding of
17 an out-of-tolerance elution result. And our Subcommittee
18 felt that was really -- that was somewhat excessive, that
19 if the licensee simply reported the out-of-tolerance
20 elution results to the vendor, and then required the
21 vendor to report to the NRC, that that would be
22 sufficient. And that's standard practice, so would not
23 introduce any additional regulatory burden on licensees.
24 We also thought it might be useful to
25 increase that reporting requirement interval from four

1 hours to 48 or even 72 hours because there might be
2 instances in which a licensee on a weekend or some such
3 thing as that where they're really short-staffed might
4 encounter such a result, and it would really be much more
5 convenient and less intrusive if there were a somewhat
6 longer reporting time interval introduced.
7 There was also -- in light of the recent
8 experience of the strontium-rubidium generator issue
9 recently as to whether the reporting rule -- the proposed
10 reporting rule is really effective and what additional
11 provisions might or might not be introduced to create a
12 more effective rule that would avoid the use of
13 out-of-tolerance elutions in terms of tear and
14 breakthrough, and thereby avoid these really major
15 disruptions of practice such as we experienced with the
16 rubidium generators. So, some of those points are
17 detailed, as well, in our report.
18 And just as we did in the case of the
19 permanent implant brachytherapy issue, we suggested that
20 the NRC solicit comments pursuant to Supplementary
21 Information Section 4D from stakeholders on whether the
22 proposed reporting requirements might discourage
23 licensees from using generators.
24 The next item, the next significant item we
25 addressed as allowing Radiation Safety Officers

1 -- Associate Radiation Safety Officers, ARSOs, to be
2 named on a medical license, and our Subcommittee strongly
3 endorsed that recommendation. We had some specific
4 comments in the specific comment section on that point.
5 The next significant issue was simply the
6 -- had to do with the plain language requirement. That's
7 Section 9. And we felt that as well written and as well
8 organized as the proposed rule was, that it perhaps could
9 be shortened and improved further by eliminating some
10 redundancies and consolidating some related sections,
11 and thereby eliminating some identical or nearly
12 identical verbiage that appears multiple times
13 throughout the draft rule.
14 Perhaps even more importantly, we felt that
15 a more detailed Executive Summary-styled section
16 summarizing maybe in the format of a bullet list the key
17 changes introduced in the proposed rule might be helpful,
18 and that would replace the current very general
19 one-paragraph summary in the proposed rule.
20 We had several other minor general
21 comments. These are detailed in our report. And then
22 beyond that, there were a number, as I said, of what we
23 characterized as significant specific comments, and a
24 number of minor or editorial specific comments. But I
25 think -- I certainly don't think it's useful to go

1 through those, so I think I'll stop at this point and
2 leave it up to Dr. Malmud if he thinks it appropriate to
3 open the report for discussion.
4 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
5 That's rather a thorough review of all the material that
6 we've been reviewing via email. And I'd like to first
7 thank you and the members of the Committee for an enormous
8 amount of work that you've done on behalf of these issues.
9 With that may we, Pat, begin with the first
10 item; if you would just remind us of the first item, we'll
11 take them in order.
12 MEMBER ZANZONICO: Yes.
13 CHAIRMAN MALMUD: By the way, I very much
14 appreciate your having numbered the lines on each of the
15 pages so that we could follow them coherently during this
16 discussion.
17 MEMBER ZANZONICO: I'm glad you found that
18 helpful. I think it would have been intractable
19 otherwise.
20 So, the first item has to do with the
21 proposed definition for medical event in permanent
22 implant brachytherapy.
23 CHAIRMAN MALMUD: Are there comments for Dr.
24 Zanzonico and members of the Committee?
25 MEMBER WELSH: Well, this is Jim Welsh, if

1 I might start.

2 CHAIRMAN MALMUD: Please do, Jim.

3 MEMBER WELSH: I appreciate that this is a

4 very complicated issue, and we've gone through years of

5 discussion, if not lively active debate on this topic,

6 and the complicated nature of this is underscored by the

7 lack of consensus presently even in a tiny Subcommittee.

8 However, I would state that in the opinion of most present

9 and past practitioners of permanent implant

10 brachytherapy, that the Permanent Implant Brachytherapy

11 Subcommittee statement is considered acceptable and

12 appropriate; and, therefore, we would not -- at least I

13 would not advocate any kind of significant changes at

14 this point. And particular reference to the historical

15 background that Dr. Zanzonico has alluded to, I would

16 point out that in that context, activity or dose might

17 have been considered acceptable or appropriate. The --

18 (Buzzer sound.)

19 MEMBER WELSH: -- is that dose is

20 absolutely not appropriate when we are talking about

21 medical event definition for the target or what we call

22 the treatment site.

23 Having said that, we would not feel that

24 dose was entirely inappropriate for medical event

25 definition if we are excluding treatment site, but

1 focusing rather on adjacent or internal normal
2 structures, and therein we have encountered some
3 controversy and lack of consensus.
4 The 5cc volume was considered necessary or
5 at least appropriate to come up with some -- it was
6 considered appropriate to come up with some volume so
7 that we're not just talking about a dose without a
8 specific volume or a volume without a specific dose. The
9 two are interrelated; otherwise, it doesn't make a whole
10 lot of sense, and is impractical.
11 We understand that the 5cc criteria might
12 not be optimal, and it is probably not ideal for prostate
13 as a specific example. But because we have used all forms
14 of permanent implant brachytherapy together in this
15 categorization in this medical event definition, we had
16 to come up with something, and 5ccs seems to be acceptable
17 for most of them. It would probably never cause much
18 difficulty for prostate. And, in specific, we are talking
19 about the refill dose which the volume to the urethra
20 -- the volume of the urethra within the prostate is often
21 not even 5ccs, so by that criterion we might never have
22 a medical event in prostate permanent implant
23 brachytherapy that has been triggered because of
24 excessive dose to an internal structure; but that for
25 other types of permanent implant brachytherapy, it would

1 be inappropriate to have something smaller than 5ccs.
2 So, we felt that sticking with the original
3 definition that was proposed by the Permanent Implant
4 Brachytherapy Subcommittee that we would have an
5 appropriate and acceptable definition that is not too
6 complex, and would not cause practitioners to avoid
7 pursuing this appropriate form of therapy for their
8 patients.
9 And when compared to the current, and what
10 I think is an inappropriate medical event definition for
11 permanent implant brachytherapy, this new definition,
12 even with the perceived complexity, is going to be in
13 practice far less complicated, and far less likely to
14 cause avoidance of brachytherapy than the present
15 situation.
16 Additionally, if we use post-implant
17 dosimetry as has been recommended but not mandated, it's
18 not going to be too difficult to implement from a
19 practical perspective. So, I don't think that we would
20 be causing practitioners to eschew permanent implant
21 brachytherapy with this new proposed medical event
22 definition.
23 Finally, as far as Compatibility C, I, for
24 one, would argue that the states should not be allowed
25 to continue to use the inappropriate medical event

1 definition based on dose to the target or treatment site;
2 and, therefore, Compatibility Category B would be most
3 appropriate. So, those are my comments on your points
4 that were brought up, Dr. Zanzonico.
5 CHAIRMAN MALMUD: Pat, do you have any
6 comments about Dr. Welsh's comments?
7 MEMBER ZANZONICO: Well, in our discussions
8 among the members of the Subcommittee, you know, I was
9 in agreement with the sentiments he expressed. I thought
10 the -- as he said, in attempting to base an ME definition
11 in part on an excessive dose to normal tissue, one has
12 to specify some volume because, as we know with seed
13 implants or with any focal sources you can get an almost
14 arbitrarily high dose to an infinitesimally small volume
15 of tissue or points in the immediate vicinity of a source
16 which has no clinical meaning, so I think it's critical
17 that some meaningful volume -- that that ME definition
18 based on -- or criteria for ME based on normal tissue dose
19 have some volume. And, frankly, I defer to others who are
20 far more knowledgeable about this -, permanent implant
21 brachytherapy, like Dr. Welsh, like Dr. Thomadsen. But
22 I think if those practitioners in that field feel that
23 it's a practical implementable criterion along with the
24 source strength-based criterion, then I'm all in favor
25 of it. And I certainly agree with Dr. Welsh that it's far

1 better than the current dose-based criteria for a
2 permanent implant brachytherapy ME.
3 The one concern I have is actually on behalf
4 of the regulators, and is that a practically inspect-able
5 criterion for a medical event. So, I would ask either Dr.
6 Welsh, or Dr. Thomadsen, or whomever, if they might
7 comment on that point, the inspect-ability of the
8 excessive dose to 5 cubic centimeters of contiguous
9 normal tissue, is that a practically inspect-able
10 criterion?
11 VICE CHAIRMAN THOMADSEN: This is Bruce
12 Thomadsen. I think it's a fairly easily achieved
13 inspection criteria.
14 CHAIRMAN MALMUD: Other comments from other
15 members of the Committee? Is there agreement among the
16 members of the Subcommittee that this is so? Could we have
17 a voice vote about it on the phone? Are all the members
18 of the Committee in agreement?
19 (Chorus of ayes.)
20 CHAIRMAN MALMUD: Are there any abstentions
21 or nays?
22 MEMBER SULEIMAN: That's for this specific
23 -- this is Orhan Suleiman. That's for this specific part
24 of the report?
25 CHAIRMAN MALMUD: Yes, we're taking them one

1 part at a time, Orhan. Thank you for clarifying that. So,
2 is there agreement on this item among all the members of
3 the Subcommittee? If so, does the Subcommittee wish to
4 make that recommendation to the Committee?
5 MEMBER ZANZONICO: Yes. So, I think just to
6 verbalize, or try to make it as explicit as possible what
7 we're recommending, we are recommending that adoption of
8 the proposed definition of a medical event for permanent
9 implant brachytherapy, that's the first point. And I
10 think it's a multi-part vote we're taking, so that would
11 be the part of the vote.
12 I guess I should ask members of the
13 Subcommittee or the ACMUI overall, do we want to formally
14 recommend to the NRC that they solicit feedback from
15 stakeholders as to whether this definition would or would
16 not discourage use of permanent implant brachytherapy,
17 or do we feel that that's not -- that's now a non-issue?
18 MEMBER LANGHORST: Dr. Malmud, this is Sue
19 Langhorst. May I speak?
20 CHAIRMAN MALMUD: Yes, Dr. Langhorst.
21 MEMBER LANGHORST: Thank you. Just one way
22 that it might be easier to go through this is, what are
23 the recommendations that we have in our written report
24 right now, and maybe go through them one by one as far
25 as this section goes. For instance, on Item A at the very

1 last sentence we say, "The ACMUI recommends NRC Staff
2 allow use of total source strength as a substitute for
3 total dose for determining medical events for permanent
4 implant brachytherapy until the Part 35 rulemaking is
5 complete."
6 Maybe if we go step by step on this, if the
7 Committee agrees with those recommendations.
8 CHAIRMAN MALMUD: Thank you. That's a
9 constructive suggestion.
10 MEMBER ZANZONICO: Agreed.
11 CHAIRMAN MALMUD: Let's move forward with
12 it.
13 MR. EINBERG: Dr. Malmud, Chris Einberg
14 here. If I may suggest, also, every time the ACMUI has
15 a recommendation, if the NRC could -- if you could
16 provide the opportunity for the NRC staff to either
17 comment on that before you guys vote that would be
18 helpful, as well.
19 CHAIRMAN MALMUD: Thank you. And are there
20 comments from the NRC staff before this item is voted
21 upon?
22 MR. EINBERG: Yes, there is; Ms. Neelam
23 Bhalla.
24 MS. BHALLA: Yes. Good afternoon, Dr. Malmud
25 and the Committee members.

1 CHAIRMAN MALMUD: Good afternoon.

2 MS. BHALLA: With regard to Item 1A, the

3 staff feels that this is not part of the --

4 CHAIRMAN MALMUD: Can you speak up, please?

5 I can't hear you.

6 MS. BHALLA: Okay. The staff feels that Item

7 1A is a historical discussion of the ME rule which has

8 been discussed a lot by the ACMUI to the point that, you

9 know, we had done a revised proposed rule, et cetera. So,

10 at this point, especially the last paragraph where it

11 says, "The ACMUI recommends to allow the source strength

12 to be used," this is part of the ongoing issue with the

13 rule, part of the proposed rule. Therefore, when we are

14 going to be presenting your report to the Commission and

15 also our staff responses, we are going to mention that

16 this 1A is not part of the proposed rule, rather than what

17 the issue is.

18 MR. EINBERG: Ms. Bhalla, this is Chris

19 Einberg once again. I think that's a useful comment;

20 however, I believe if the ACMUI would like to make that

21 recommendation, you can state in the rulemaking that this

22 is outside the scope of the rule. This, however, may be

23 useful to the staff as we consider our enforcement

24 policy, so it is a useful comment. So, I would just state

25 that if the ACMUI still would like to make that

1 recommendation, we'll certainly entertain that
2 recommendation.
3 MEMBER ZANZONICO: This is Pat Zanzonico. I
4 think it would be useful to include that recommendation
5 even if it were ultimately determined to be outside the
6 scope of not only the proposed rule but the ACMUI's review
7 of the proposed rule because, if nothing else, it would
8 reinforce the unanimous preference for an activity-based
9 ME criteria as opposed to the existing dose-based
10 criteria. So, I think it would be a useful recommendation
11 to have on the record, nonetheless.
12 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
13 And I think that the members of the Subcommittee and
14 members of the Committee agree with you. Someone said
15 something but they were far away from the speaker and it
16 didn't come through. Can you repeat what you said?
17 MS. HOLIDAY: Dr. Malmud, this is Sophie. I
18 just wanted to make a quick announcement for all parties
19 that are on the teleconference call.
20 CHAIRMAN MALMUD: Yes?
21 MS. HOLIDAY: For all members of the public
22 and for participants who are on the ACMUI or who are staff
23 members that are participating, if you are not speaking
24 at the time, if you would please mute your phone. If your
25 phone does not have that capability you can press *6 and

1 that will mute it for you.

2 Also, while this has already been happening

3 so far, for members that are speaking please state your

4 name so that we can get on the record for the court

5 reporter.

6 CHAIRMAN MALMUD: Thank you, Sophie.

7 MS. HOLIDAY: Thank you.

8 MEMBER WELSH: This is Dr. Welsh.

9 CHAIRMAN MALMUD: Yes, Dr. Welsh?

10 MEMBER WELSH: I apologize to Dr. Zanzonico.

11 He was asking a specific question, and my name came up,

12 and there was a technical failure, and I missed a minute

13 or two of the conversation. If there was anything that

14 I was specifically asked to address, I'm back here again,

15 but I apologize for being out of touch for the past two

16 minutes.

17 CHAIRMAN MALMUD: Thank you. I'm not aware

18 that you were asked to address anything specifically

19 except with regard to your agreement or disagreement with

20 the rest of the Committee -- Subcommittee's

21 recommendation.

22 MEMBER GUIBERTEAU: Dr. Malmud?

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

24 MEMBER GUIBERTEAU: This is Mickey

25 Guiberteau.

1 CHAIRMAN MALMUD: Yes, Dr. Guiberteau.

2 MEMBER GUIBERTEAU: Could I -- I can't find

3 a document that has been sent to me that actually gives

4 the members of the Subcommittee. And I can't remember who

5 they might be, but in this discussion, I was not a member

6 of the Subcommittee. It would be helpful for me to know

7 from the -- in that context which speakers are speaking

8 from inside the Committee; that is, they had the benefit

9 of the discussions, and those who may be, you know -- who

10 may have differences with the opinions of the

11 Subcommittee. So, if we could have that information, I

12 think it would be helpful to me and perhaps to those

13 members of the public and others who are listening to this

14 call.

15 CHAIRMAN MALMUD: Thank you. Would you like

16 that emailed to you, the list of the Subcommittee, as

17 opposed to --

18 MEMBER GUIBERTEAU: That would be fine for

19 me, if that's the way we're doing it.

20 CHAIRMAN MALMUD: Find it. Sophie, is it

21 possible to do that now during the conference call?

22 MS. HOLIDAY: Would it more beneficial if I

23 go ahead and announce who those Subcommittee members were

24 on the phone?

25 CHAIRMAN MALMUD: All right. If the

1 interested parties have pencils handy you can write down
2 these names.
3 MS. HOLIDAY: Sure, and it will also be
4 included in the transcript on the record.
5 CHAIRMAN MALMUD: Yes.
6 MS. HOLIDAY: So, the Subcommittee
7 Chairperson was Dr. Pat Zanzonico. Additional members
8 include Dr. Susan Langhorst, Mr. Steve Mattmuller, Ms.
9 Laura Weil, Dr. Bruce Thomadsen, and Dr. James Welsh.
10 MEMBER GUIBERTEAU: Thank you very much.
11 MS. HOLIDAY: You're welcome.
12 CHAIRMAN MALMUD: All right. I believe that
13 we had a statement that there was agreement amongst the
14 members of the Subcommittee with regard to Dr.
15 Zanzonico's recommendation, and it was unanimous. So, we
16 hope that the Minutes will reflect that.
17 Can we move on to the next item, Dr.
18 Zanzonico?
19 MEMBER ZANZONICO: Yes. So, this -- in terms
20 of an actionable item, that would be Item C in Section
21 1; and that is whether to recommend to the NRC -- this
22 is Pat Zanzonico, by the way. Whether we recommend to the
23 NRC that it solicits feedback from stakeholders on
24 whether the proposed ME definition for permanent implant
25 brachytherapy would discourage licensees from using this

1 form of therapy. The alternative is whether we feel now
2 that that would not be the case. I inferred from some of
3 Dr. Welsh's comments that that was his feeling at the
4 moment. So, to put a point on it, should we offer this
5 recommendation or not to the NRC on soliciting feedback?
6 MS. HOLIDAY: Dr. Zanzonico and Dr. Malmud,
7 this is Sophie, if I could interject real quick. I believe
8 the initial recommendation on the table was for the
9 recommendation that was in 1A, so we wanted just a little
10 bit of clarification. I heard that Dr. Malmud said that
11 the Subcommittee had --
12 (Paper shuffled.)
13 MS. HOLIDAY: I do not believe that
14 recommendation was put before the full Committee.
15 CHAIRMAN MALMUD: You are correct, Sophie.
16 The Subcommittee unanimously approved it. We can now put
17 it before the full Committee whose members I believe
18 represent a quorum on this phone, on this teleconference.
19 So, therefore, we will put the same motion before the full
20 Committee. Are any -- all in favor?
21 (Chorus of ayes.)
22 CHAIRMAN MALMUD: Any opposed? Any
23 abstentions?
24 (No response.)
25 CHAIRMAN MALMUD: So, the motion carries

1 unanimously.

2 MS. HOLIDAY: Thank you.

3 CHAIRMAN MALMUD: Thank you, Sophie, for the

4 clarification. Dr. Zanzonico, you're on again.

5 MEMBER ZANZONICO: Okay. So, the point I was

6 addressing was Point C, and whether or not we should make

7 a formal recommendation to solicit input as to the impact

8 of the proposed ME definition. So, again, I was

9 specifically addressing my comments to Dr. Welsh and Dr.

10 Thomadsen and, of course, whoever else would care to

11 offer an opinion on the Subcommittee or Committee. But

12 what is the feeling at this point on that possible

13 recommendation?

14 VICE CHAIRMAN THOMADSEN: This is Bruce

15 Thomadsen, and having been at a stakeholders' meeting on

16 this issue in the past, I think we've heard from

17 stakeholders on their preferences. We could do that. I

18 don't think we'll gain much information that we don't

19 already have.

20 MEMBER WELSH: This is Jim Welsh here. I

21 concur with what Bruce has just said. In my introductory

22 statement, I pointed out that we've been debating and

23 discussing this for several years now, and it's apparent

24 that we're never going to get something that is 100

25 percent perfect. But I believe that what we have

1 currently on the table is as close as we're going to get,
2 and although I have no major objection to additional
3 input from stakeholders and societies, I agree with
4 Bruce, that I doubt very much that we're going to have
5 any major changes or alternatives that are being proposed
6 seriously. And, therefore, my concern is one of
7 efficiency.
8 If this process would in any way slow things
9 down, I would not be in favor of it. If it would be
10 time-neutral I have no objections to it, but I don't
11 personally see what would be gained from it.
12 MEMBER ZANZONICO: Okay. This is Pat
13 Zanzonico. So, my perception then is that we can forego
14 that recommendation unless there's any other comment by
15 members of the Subcommittee or the ACMUI. I would suggest
16 that we just forego that item all together then.
17 MEMBER LANGHORST: Pat, this is Sue
18 Langhorst. May I speak?
19 MEMBER ZANZONICO: Please.
20 MEMBER LANGHORST: Okay. I do not share Jim's
21 opinion that this would -- I think we should keep this
22 recommendation. And if we don't keep this
23 recommendation, I would hope that stakeholders will
24 comment on it in their comments on the proposed rule when
25 it is published. So, I think it's not a bad idea to propose

1 this question be asked of stakeholders, but I am not
2 opposed to it being dropped out of this recommendation.
3 MEMBER ZANZONICO: Dr. Malmud, could we then
4 -- unless there is any further comments, can we then move
5 to a vote? And if we follow the model we did on the
6 previous point, we'll have a vote of the Subcommittee
7 followed by a vote of the whole ACMUI?
8 CHAIRMAN MALMUD: Yes. Are all the members
9 of the -- we'll first poll the Subcommittee members. All
10 in favor?
11 (Chorus of ayes.)
12 MS. BHALLA: Dr. Malmud.
13 CHAIRMAN MALMUD: Yes?
14 MS. BHALLA: Yes, this is Neelam Bhalla from
15 NRC.
16 CHAIRMAN MALMUD: Yes.
17 MS. BHALLA: We here discussed also this
18 question and staff thinks that this question, even if we
19 want to keep it perhaps could be phrased in a different
20 way, and we could ask the licensees if the proposed new
21 definition has the clarity, and if it meets the
22 requirements of the working physicians, because when the
23 SRM was issued on this subject, the Commission was very
24 clear on -- to us, to the Staff that it should be -- it
25 should not impede on the practicing physicians; and, yet,

1 it should protect the interest of the patients. And,
2 therefore, we brought this -- the proposed rule is pretty
3 much based on what the ACMUI's recommendations were. So,
4 we could perhaps ask the question in our proposed rule
5 is it -- is the definition clear enough rather than
6 saying about this, you know, if it's going to discourage
7 licensees from using this therapy option.
8 CHAIRMAN MALMUD: Are you suggesting
9 different wording?
10 MS. BHALLA: Yes.
11 CHAIRMAN MALMUD: Do you have the specific
12 wording that you would like to suggest?
13 MS. BHALLA: We could propose something.
14 Actually, we could say doctors, if you must keep
15 something -- in the Statements of Consideration, if you
16 have seen we do ask in general questions about how this
17 rulemaking is going to impact. We do ask general
18 questions, so either we can just leave this right here
19 and because we have the other questions in general, so
20 we could just leave it there, or for the ME definition
21 we could ask -- the language could be, is this revised
22 definition clear enough or -- I didn't bring the right
23 words, the exact words, but something to that effect,
24 rather than it's going to impact the practice.
25 CHAIRMAN MALMUD: So, the staff would prefer

1 to see wording other than it's -- the current wording
2 which suggests that it might impact practice. Is that
3 correct?
4 MS. BHALLA: That is correct.
5 CHAIRMAN MALMUD: All right. Dr. Zanzonico,
6 do you have a suggestion?
7 MEMBER ZANZONICO: Yes. How about -- so we
8 can say should the NRC -- the recommendation or the vote
9 would be on the following. Should the NRC solicit
10 stakeholder feedback on whether the proposed ME
11 definition for permanent implant brachytherapy is
12 sufficiently clear in language to not adversely effect
13 clinical practice.
14 CHAIRMAN MALMUD: Thank you. Does that meet
15 the spirit of the request? That's to NRC staff, the
16 question.
17 MS. BHALLA: We believe we should not bring
18 in the concept of the -- what was that word again?
19 MEMBER ZANZONICO: Well, is the proposed ME
20 definition sufficiently clear in language to not
21 adversely impact clinical practice?
22 MS. BHALLA: We just want to discuss that
23 here for a second.
24 MEMBER LANGHORST: Dr. Malmud, this is Sue
25 Langhorst.

1 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

2 MEMBER LANGHORST: I would like to say that

3 I think the intent here is just to pose a question of the

4 impact of this change, and I think the NRC staff does not,

5 necessarily, have to follow the exact language of a

6 recommendation here, but to ask that type of question,

7 as Neelam was describing to see how this change in medical

8 event definition impacts the practitioners.

9 MEMBER ZANZONICO: This is Pat Zanzonico. I

10 think Dr. Langhorst's point is very well taken. I think

11 we can leave it to the NRC to formulate the exact language

12 of the inquiry but, basically, some feedback should be

13 solicited on the possible clinical impact of the proposed

14 ME definition. But I would feel comfortable leaving it

15 to the NRC to devise the exact language.

16 One other -- if I may, one other point I'd

17 like to raise, and I think it was a point that Dr. Welsh

18 introduced, and it's a very good one. I presume that this

19 solicitation of information would basically be part of

20 in a sense that general public review of the proposed rule

21 so that it should not slow things down. In other words,

22 it would be done in parallel with soliciting other

23 comments, and so forth, rather than in series, so it

24 should not slow things down, which I think is something

25 we all want to avoid. Is that everyone's sense, as well?

1 CHAIRMAN MALMUD: I suspect that it is, Dr.
2 Zanzonico. I don't think anyone would -- well, I
3 shouldn't speak for the rest of the Committee, but I don't
4 believe any of the members of the Committee would object
5 to what you just said. Am I correct in that? I hear no
6 dissension from members of the Committee, so we fully
7 agree with you.
8 MEMBER WELSH: This is Dr. Welsh, if I might
9 just add a quick comment.
10 CHAIRMAN MALMUD: Dr. Zelac?
11 MEMBER WELSH: Welsh.
12 CHAIRMAN MALMUD: Oh, Dr. Welsh.
13 MEMBER WELSH: I suppose I would acquiesce
14 and agree to go along with having this solicitation of
15 input from stakeholders, but I would remind the Committee
16 as a whole that this is essentially the ASTRO definition
17 with a couple of minor modifications. So, although we're
18 not going to have complete unanimity from the entire
19 stakeholder population, this is essentially a society,
20 specifically ASTRO, the ASTRO proposed definition that
21 has been published and discussed repeatedly at the NRC,
22 the various stakeholder meetings, and within the ACMUI
23 and other venues.
24 So, I suppose my point is that although I'm
25 not opposed to seeking additional stakeholder input at

1 this point, to me, I think it's a moot point because we're
2 basically using the ASTRO definition. And my major
3 concern is that if there is any possibility that this is
4 going to slow things down, my vote would be in favor of
5 not allowing anything that could slow things down, to
6 move on.
7 CHAIRMAN MALMUD: Thank you, Dr. Welsh.
8 VICE CHAIRMAN THOMADSEN: And this is Bruce
9 Thomadsen. I will just point out that one of the other
10 major stakeholders was the American Brachytherapy
11 Society, also agreed that they like the ASTRO definition.
12 CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.
13 May we move on? So, we're entrusting the final wording
14 to the NRC, and the Committee is supportive of that. So,
15 Dr. Zanzonico, we're on to the next item.
16 MS. BHALLA: Well, Dr. Malmud.
17 CHAIRMAN MALMUD: Yes?
18 MS. BHALLA: Yes, this is Neelam Bhalla
19 again. We just -- staff would like to just re-emphasize
20 that we are soliciting -- first of all, a proposed rule
21 is soliciting public -- the whole idea of a proposed rule
22 is to solicit comments from public which would mean
23 licensees. And we have already included in our -- under
24 Section 4 under Discussion, we start with what actions
25 is the NRC taking, and then we are specifically bringing

1 to the public's attention where the changes would be.
2 And, therefore, this particular question to put it like
3 that, if it's going to impact the practice, is not
4 appropriate, so we just want to make that notation here,
5 that the question is already asking the public. And,
6 therefore, we should not be asking a specific question
7 in terms of exactly, you know, how it's going to impact
8 the practice.
9 CHAIRMAN MALMUD: Thank you. Dr. Zanzonico?
10 MEMBER ZANZONICO: Again, I have no
11 objection to leaving it to the NRC Staff to -- in however
12 they typically formulate solicitations for feedback. And
13 it's understood that just requesting public comment is,
14 in effect, accomplishing the same thing. So, I have no
15 objection if the NRC feels it's necessary to eliminate
16 the specific language, that there'll still be
17 opportunity for stakeholders to offer whatever comments
18 they may have without specifically soliciting comments
19 on impact on clinical practice.
20 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
21 MEMBER LANGHORST: Dr. Malmud, this is Sue
22 Langhorst.
23 CHAIRMAN MALMUD: Yes, Dr. Langhorst.
24 MEMBER LANGHORST: Are we keeping C, or are
25 we not keeping C?

1 CHAIRMAN MALMUD: Dr. Zanzonico?

2 MEMBER ZANZONICO: Good question, Sue. I
3 would suggest that -- well, I would suggest this, let's
4 vote explicitly on retaining Point C as currently worded.
5 And I think the further discussion may be moot once we
6 have a vote, but I would suggest we vote on retaining the
7 language as it's currently presented in the report.

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

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

15 CHAIRMAN MALMUD: Yes, Dr. Zanzonico. Do the
16 members of the Subcommittee approve?

17 MEMBER LANGHORST: I approve.

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

21 MEMBER ZANZONICO: Yes, please.

22 CHAIRMAN MALMUD: Now members of the entire
23 Committee that have voting privileges, is there anyone
24 opposed to this motion which has been approved by the
25 Subcommittee? Are there any abstentions? I will assume,

1 therefore, that all the other votes are positive. Once
2 again you have unanimity, Dr. Zanzonico.
3 MEMBER ZANZONICO: Very good, thank you.
4 So, the next item, this would be Item 1D.
5 And I think this is very explicit, and that is that the
6 Subcommittee recommends that the proposed rule for
7 redefining MEs in permanent implant brachytherapy be
8 designated as Compatibility Category B rather than C.
9 CHAIRMAN MALMUD: Thank you. That's a motion
10 from the Subcommittee?
11 MEMBER ZANZONICO: Correct.
12 CHAIRMAN MALMUD: And the Subcommittee
13 members have approved that thus far.
14 MEMBER ZANZONICO: Well, we can have a vote.
15 CHAIRMAN MALMUD: Okay. All in favor
16 -- these are members of the Subcommittee. All in favor?
17 (Chorus of ayes.)
18 CHAIRMAN MALMUD: Any opposed? Any
19 abstentions?
20 (No response.)
21 CHAIRMAN MALMUD: There's unanimity. May we
22 take that now to the whole Committee? All in favor?
23 MEMBER LANGHORST: Dr. Malmud, this is Sue
24 Langhorst.
25 CHAIRMAN MALMUD: Dr. Langhorst?

1 MEMBER LANGHORST: Yes, you may want to ask
2 the staff for their opinion on this before it goes to the
3 whole Committee.
4 CHAIRMAN MALMUD: Thank you for reminding
5 me, Dr. Langhorst. The opinion of the staff?
6 MR. EINBERG: Yes. This is Chris Einberg. We
7 don't have anybody from the Agreement States Program
8 here, so we have no comment at this point.
9 CHAIRMAN MALMUD: Thank you, Chris. Members
10 of the Committee as a whole, any objections? Any
11 abstentions?
12 (No response.)
13 CHAIRMAN MALMUD: Hearing none, it's
14 unanimous again. Thank you, and we'll move on to the next
15 item. Dr. Zanzonico.
16 MEMBER ZANZONICO: Yes. So, this would
17 -- and I think this is -- I can't imagine this would be
18 contentious, Item 1E. And the recommendation would be to
19 replace the phrasing in the literature or to the
20 literature in terms of support for the 5 cubic centimeter
21 of contiguous normal tissue provision of the ME
22 definition, to replace the "literature" phrasing with
23 the specific references cited, that's Nag, et al 2004.
24 So, can the Subcommittee -- would the members of the
25 Subcommittee vote on approving that revision?

1 CHAIRMAN MALMUD: All the members of the
2 Subcommittee who approve please say aye.
3 (Chorus of ayes.)
4 CHAIRMAN MALMUD: Any opposed? Any
5 abstentions?
6 (No response.)
7 CHAIRMAN MALMUD: You've achieved unanimity
8 again, Dr. Zanzonico. If we may, any comments from NRC
9 Staff?
10 MS. BHALLA: Yes, this is Neelam Bhalla. We
11 just want to thank the Committee, the Subcommittee on
12 this.
13 CHAIRMAN MALMUD: Thank you, Ms. Bhalla. Now
14 take it to the entire Committee. All in favor?
15 (Chorus of ayes.)
16 CHAIRMAN MALMUD: Any objections? Any
17 abstentions?
18 (No response.)
19 CHAIRMAN MALMUD: Once again unanimity.
20 Thank you, Dr. Zanzonico. Next item?
21 MEMBER ZANZONICO: Okay. So, now we're to
22 Item 2, and this is on the training and experience issue.
23 And the first actionable item is 2B. And the basic
24 recommendation is to eliminate the explicit requirement
25 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.

MEMBER ZANZONICO: Correct. Thank you, Sue.

MEMBER LANGHORST: Okay, thank you.

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

CHAIRMAN MALMUD: Yes, Steve?

MEMBER MATTMULLER: I'm -- maybe I'm asking for help from the NRC Staff. I'm not sure, because as I read the proposed reg, it was really more as far as in regards to generator training, was that it could be provided by an authorized nuclear pharmacist, or an ANP. And I think the Subcommittee now has gone an additional

1 step of trying to create a special category that only if
2 the licensee has a generator should then that authorized
3 user have this specialized training, which is where I
4 think it's gone. And at this point, I'm not sure I agree
5 with that. Especially from a perspective that even though
6 the vast majority of sites do have generators, a lot of
7 those same sites still get bulk technetium in the
8 afternoon for evening emergency procedures using such
9 kits as MAA and/or Ultra Tag. So, I mean, personally I
10 believe it's important that the authorized user get this
11 type of training. Thank you.
12 CHAIRMAN MALMUD: Thank you. Any comments
13 with regard to Steve Mattmuller's comments?
14 MEMBER SULEIMAN: This is Orhan Suleiman.
15 CHAIRMAN MALMUD: Dr. Suleiman.
16 MEMBER SULEIMAN: I'm more concerned with
17 -- I sort of agree with the Subcommittee in that we don't
18 want to burden authorized users who may not be using the
19 generator with that sort of training. However, I'm more
20 concerned with the flip side of that, that people who
21 actually use generators, based on our observations over
22 the last few years when we've had problems in the field,
23 apparently don't understand how generators work. And
24 there have been some safety issues because of that, so
25 I don't know if it comes here, but I sympathize with the

1 need not to burden people who don't use the generators
2 with learning how to use them, but we'll discuss this
3 latter issue when we get further on into the Subcommittee
4 report.
5 CHAIRMAN MALMUD: Thank you for your
6 comments, Dr. Suleiman.
7 MEMBER GUIBERTEAU: Dr. Malmud.
8 CHAIRMAN MALMUD: Yes?
9 MEMBER GUIBERTEAU: This is Mickey
10 Guiberteau.
11 CHAIRMAN MALMUD: Yes, Dr. Guiberteau.
12 MEMBER GUIBERTEAU: You know, I think this
13 is a -- as I have read in a number of emails and articles,
14 this is -- the issue of generators has morphed from a
15 rather simple device to one, you know, a concept that's
16 become very complex. It is exceedingly large and growing
17 burden on residencies in nuclear medicine, as well as
18 diagnostic radiology, nuclear radiology, and now even
19 cardiology with intimate contact and experience with
20 generators that will likely never be used by the AUs
21 practicing clinical medicine.
22 I think this is a very important issue, and
23 I also think to Orhan's point that while we may be
24 training and getting experience for everyone, that
25 experience might be somewhat -- terms of bolstering

1 confidence in AUs, might be a little bit unrealistic
2 simply because in real practice it might give us the false
3 sense that people have intimate contact with all sorts
4 of generators when they really don't when they go in
5 practice. So, I mean, I think -- I agree with the
6 Subcommittee. I think that this doesn't -- I agree that
7 this part of the proposed rule is really too much of a
8 burden and likely doesn't accomplish what we would like
9 it to accomplish.
10 CHAIRMAN MALMUD: Thank you for your
11 comment, Dr. Guiberteau. Dr. Suleiman, do you wish to
12 comment on that?
13 MEMBER SULEIMAN: I sort of concur with what
14 he said. So, on this part of the Subcommittee report, I
15 also agree. Why burden an authorized user with operating
16 a generator when that individual may not operate the
17 generator, and it may lead to a false sense of knowing
18 how to operate it.
19 CHAIRMAN MALMUD: All right, thank you.
20 MEMBER PALESTRO: Dr. Malmud, Chris
21 Palestro. May I speak?
22 CHAIRMAN MALMUD: Yes, please.
23 MEMBER PALESTRO: Okay. I certainly agree
24 with the Subcommittee's comment. I think the number of
25 sites that use generators are few to begin with nowadays,

1 and probably decreasing; that to insist that every AU
2 receive work experience in a generator is probably
3 impractical, and not very useful. And I would think that
4 it would be more appropriate for those AUs who are using
5 generators to receive generator-specific training for
6 the type of generator that they use.
7 CHAIRMAN MALMUD: Thank you for that
8 comment. I suspect a number of us agree with you. Dr.
9 Zanzonico?
10 MEMBER VAN DECKER: Can I add one other
11 thought, one other voice? This is Bill Van Decker.
12 CHAIRMAN MALMUD: Yes, Dr. Van Decker.
13 MEMBER VAN DECKER: You know, I think that
14 I would agree with the concepts of some of my other
15 colleagues here. I think that, obviously, what is a
16 generator and how does a generator work is a general topic
17 that everyone needs to know as part of the AU training
18 experience. It would indeed be true that, you know, if
19 you're going to be using a generator you should be pretty
20 well versed in what that generator is, recognizing that
21 there may be newer generator systems coming on line in
22 the future. I think the only thing for us to keep in the
23 back of our minds is -- and I think Dr. Suleiman pointed
24 this out as we get further on, what does that
25 generator-specific training look like, when one adds a

1 modality to one's practice, is it really just the
2 learning of the generator, which I think it should be
3 rather than just the Radiation Safety principles of a
4 generator which is general knowledge in the AU category.
5 And, certainly, we have models for adding modalities and
6 a variety of other regs especially in Radiation Onc-type
7 realm, but I just think it's something for us to keep in
8 mind as we move forward.
9 CHAIRMAN MALMUD: Thank you for that
10 comment. Dr. Zanzonico, we're back to you.
11 MEMBER ZANZONICO: Yes. So, I think the
12 recommendation then becomes --
13 MS. BHALLA: Excuse me, Dr. Malmud.
14 MEMBER ZANZONICO: Yes?
15 MS. BHALLA: This is Neelam Bhalla, and I
16 just wanted to say that we -- when we started this
17 rulemaking it was based on what are called these user need
18 memos. It's the need that the implementing division or
19 Program office has to revise these regulations. And in
20 that the need was expressed that this training could be
21 provided. It's in the existing regs, and the training
22 could be provided by authorized nuclear pharmacists
23 along with the other of the authorized users. So, as you
24 know, the rule is due to the Commission very soon. And,
25 therefore, this will be changing the scope of the

1 rulemaking. And, therefore, we just wanted you to know
2 that the request was only to allow the nuclear
3 pharmacists to be able to give this training. So,
4 therefore, the rule is being amended to do that, and we
5 may not be able to at this point go over if AU need that
6 training, of it's possible for them, because that's like
7 starting an issue. And at this point, it's -- not be able
8 to entertain it.
9 MEMBER ZANZONICO: This is Pat Zanzonico.
10 So, if I can understand the intent of this passage in the
11 proposed rule is not to require, necessarily, supervised
12 work experience on generator elution and so forth, but
13 if such training -- if such supervised work experience
14 is provided, it could be provided by an authorized
15 nuclear pharmacist, as well as an authorized user. Is
16 that correct?
17 MS. BHALLA: Yes. What is correct is that
18 it's in the existing training requirement, so the fact
19 that should they be trained in that aspect, that was not
20 on the table, but it was who could provide that training.
21 So, the reg says -- we are amending the regs that this
22 training can be provided by the authorized pharmacists,
23 because they have as much know-how in this system as
24 anybody else. So, no, we are not changing the current
25 training requirement per se, but only who can actually

1 give that training.

2 MEMBER ZANZONICO: Okay, understood. So, I

3 would -- this is Pat Zanzonico again. I think given that,

4 I would concede that I misunderstood what was being

5 proposed. And in that case, I would suggest withdrawing

6 this recommendation.

7 MEMBER LANGHORST: Pat, this is Sue

8 Langhorst. I disagree with you. I would -- the questions

9 are there. It's not really any recommendation other than

10 questions as to why this is necessary. And I think based

11 on some of the comments of our colleagues and on the

12 Committee, it's a fair question to ask, and I would

13 recommend that it stay in here.

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

15 Pat Zanzonico again. In that case, certainly we can leave

16 our report as is with comments and questions, some

17 actionable items, some non-actionable items. Would you

18 feel comfortable just leaving this particular item as is

19 without couching it in the form of a formal

20 recommendation?

21 MEMBER LANGHORST: Yes, I would. There is no

22 real recommendation here of ACMUI. It's just raising

23 those questions, and proposing an alternative of how NRC

24 Staff could handle this type of thing in the future.

25 MEMBER ZANZONICO: Understood.

1 MEMBER GUIBERTEAU: Pat.

2 MEMBER ZANZONICO: Yes?

3 MEMBER GUIBERTEAU: This is Mickey
4 Guiberteau, may I offer a comment?

5 MEMBER ZANZONICO: Please.

6 MEMBER GUIBERTEAU: You know, I -- putting
7 aside for a moment whether or not AUs in 298 need
8 generator on-hands experience, if it is going to be
9 continued to be required, which is what I understood is
10 preferred, it is very important that authorized
11 pharmacists be able to provide this, because in many
12 institutions the only place they're able to get it is by
13 sending their residents to a commercial pharmacy where
14 a pharmacist, a nuclear pharmacist is the person
15 providing the training. And in the past that has been
16 somewhat questioned since in most of the rule you have
17 to have someone providing that training who is actually
18 performing -- an AU in the same areas, clinical areas of
19 the rule. So, I don't want to let --I would prefer that
20 not be lost in this because if we're keeping the training
21 requirement the same, it would be very helpful to know
22 who we can go to, to whom we may go to get this training.

23 MEMBER ZANZONICO: Understood. My
24 understanding is that the proposed rules would allow
25 nuclear pharmacists to provide the training, and at the

1 same time I think in retaining the language in Item 2B,
2 as Sue suggests, isn't contrary to that.
3 MEMBER GUIBERTEAU: All right.
4 CHAIRMAN MALMUD: Therefore, I understand
5 that we will leave it in, recognizing that it will not
6 be acted upon, but it will certainly convey the spirit
7 of the ACMUI and the Subcommittee to whoever reads it.
8 MEMBER ZANZONICO: Pat Zanzonico. That would
9 be my suggestion and my understanding, as well.
10 CHAIRMAN MALMUD: Thank you. And do we have
11 approval of the members of the Subcommittee for this? Any
12 objections or abstentions? If not, are there any
13 objections or abstentions from the Committee having
14 heard the comments of NRC staff already?
15 (No response.)
16 CHAIRMAN MALMUD: Hearing none I assume that
17 it's, therefore, approved unanimously.
18 MR. EINBERG: Dr. Malmud, Chris Einberg
19 here.
20 CHAIRMAN MALMUD: Yes, Chris.
21 MR. EINBERG: Does the Committee want to
22 endorse the current language right now also, that the NRC
23 Staff has proposed in the rule to allow the nuclear
24 pharmacist to do the training?
25 CHAIRMAN MALMUD: Yes, that was -- I believe

1 that was what Dr. Zanzonico was proposing. Am I correct,
2 Pat?
3 MEMBER ZANZONICO: Well, actually, I was not
4 thinking of this as a -- we're not calling an actionable
5 item, in other words, a votable item at all. But I think
6 that's not unreasonable. So, yes, we could have a vote
7 on the language, and it's in lines 1447 to 1448 on page
8 48 that says, "ANPs have the T&E to provide the supervised
9 work experience for AUs on the elution of generators."
10 Again, as was pointed out, it's simply allowing ANPs,
11 it's authorizing ANPs to provide that training.
12 CHAIRMAN MALMUD: All members of the
13 Subcommittee in favor, please say aye.
14 (Chorus of ayes.)
15 CHAIRMAN MALMUD: Any opposed? Any
16 abstentions?
17 (No response.)
18 CHAIRMAN MALMUD: All right. That's the
19 motion of the Subcommittee. Does NRC staff wish to make
20 a comment before we take it to the whole Committee?
21 MS. BHALLA: No, we are fine, thank you.
22 CHAIRMAN MALMUD: Thank you. The entire
23 Committee, we'll consider this a motion from the members
24 of the Subcommittee. All in favor?
25 (Chorus of ayes.)

1 CHAIRMAN MALMUD: Any objections? Any
2 abstentions?
3 (No response.)
4 CHAIRMAN MALMUD: Hearing neither
5 objections nor abstentions, it passes unanimously. Thank
6 you. We'll move on to the next item.
7 MEMBER ZANZONICO: So the next item is Item
8 2-C. We're still on training and experience. And it's
9 a proposed change in language. And the language, and
10 this appears at multiple points in the proposed rule.
11 The current language in the proposed rule
12 is that preceptors would attest that trainees or
13 candidates have satisfactorily fulfilled the training
14 and experience requirements consistent with achieving,
15 I'm sorry.
16 What the proposed rule said, have
17 satisfactorily completed the necessary training and
18 experience requirements, and has achieved a level of
19 competency sufficient to function independently in the
20 position for which the authorization is sought. That's
21 the current language.
22 The language being proposed, the
23 alternative language being proposed is, "Has
24 satisfactorily fulfilled the training and experience
25 requirements consistent with achieving a level of

1 competency sufficient to function independently in the
2 position for which the authorization is sought."
3 So again, the distinction is the preceptor
4 attesting that the candidate has achieved a level of
5 competency. The alternate language being proposed is
6 simply asking the preceptor to attest that the candidate
7 has completed training and experience consistent with
8 achieving that competency. So what we're voting on is
9 replacing that current language with the alternative
10 language.
11 MS. BHALLA: Yes, Dr. Malmud?
12 CHAIRMAN MALMUD: Yes.
13 MS. BHALLA: The staff wants to speak on
14 this a little bit.
15 CHAIRMAN MALMUD: Please do.
16 MS. BHALLA: And Susan Chidakel from NRC is
17 going to. Because I think it's somewhat misunderstood.
18 MS. CHIDAKEL: Hi. Thank you for letting
19 me interject here. I think you have misread the language.
20 The language that you're talking about, you've taken out
21 of our summary of what we're changing.
22 And what the language that you're talking
23 about- it says, "the attestation must state that the
24 individual has satisfactorily completed." That's the
25 language that's in the rule now.

1 We're proposing to take that language out
2 completely and change that whole thing, and take out the
3 reference to competence.
4 If you look at the actual rule text, for
5 example if you look at Page 98 or 99 for actual rule text
6 that's in the rule itself, you'll see that competence
7 language is not in there.
8 So I think you've misunderstood what we were
9 doing here. We weren't trying to tell you what we were
10 going to try to change to put in something about
11 competence. We were summarizing the state of affairs
12 right now.
13 MEMBER ZANZONICO: In that case, this is
14 Pat Zanzonico, in that case then I didn't misunderstand.
15 MS. CHIDAKEL: You did not misunderstand?
16 MEMBER ZANZONICO: No, I did, based on what
17 you're just telling me now. It was my understanding,
18 clearly mistaken, that this was the language in the new
19 language.
20 MS. CHIDAKEL: No. Take a look, for example,
21 at Page 99. If you look at B-2, you'll see a sample of
22 what -- this is for the authorized nuclear pharmacist.
23 You'll see a sample of what the preceptor is going to be
24 attesting to now, in the new proposed rule, just as an
25 example.

1 And you can look at several sections. You
2 can see the same thing on Page 98, with regard to the
3 authorized medical physicist. I just picked out a couple
4 at random.
5 MEMBER ZANZONICO: I don't know if you have
6 the line numbers. Is it possible you can identify the line
7 numbers?
8 MS. CHIDAKEL: On Page 98 it starts on, B
9 starts on 2899. And then it's on 2900, it says too, have
10 obtained written attestation. Do you see that there?
11 MEMBER ZANZONICO: Right.
12 MS. CHIDAKEL: Okay. Then just keep reading
13 on down.
14 MEMBER ZANZONICO: Okay.
15 (Off the record comments)
16 MS. BHALLA: 2901.
17 MS. CHIDAKEL: I'm sorry?
18 MS. BHALLA: 2901.
19 MS. CHIDAKEL: Did I get the wrong line?
20 Here it is, right. Thank you, Neelam, 2901, "Is able to
21 independently fulfill the radiation safety related
22 duties as an authorized medical physicist for each type
23 of therapeutic medical unit for which the individual,"
24 et cetera, et cetera, et cetera.
25 And you see there's nothing in here about

1 competence. And even more clearly, if you flip the page
2 to Page 99, and look at line 2927 --
3 MEMBER ZANZONICO: Yes.
4 MS. CHIDAKEL: Two, "Has obtained written
5 attestation signed by the preceptor authorized nuclear
6 pharmacist, the individual has satisfactorily completed
7 the requirements in B-1, and us able to independently
8 fulfill the radiation safety related duties of an
9 authorized nuclear pharmacist." There's nothing in
10 here about competency anymore.
11 MEMBER ZANZONICO: Understood.
12 CHAIRMAN MALMUD: This is Malmud, that's
13 wonderful. Because we've struggled with that term for a
14 long time, and very much appreciate the wording that's
15 now in the document.
16 MEMBER ZANZONICO: That is why, this is Pat
17 Zanzonico, I acknowledge my misunderstanding. And on
18 that basis, am happy to withdraw consideration of this
19 recommendation.
20 CHAIRMAN MALMUD: Thank you.
21 MEMBER ZANZONICO: Although having said
22 that, I think it emphasizes the need for a more explicit
23 executive summary type statement.
24 CHAIRMAN MALMUD: This is Malmud, were you
25 referring to something specific?

1 MEMBER ZANZONICO: No, again, it was just,
2 I felt I read the document carefully, and this other
3 language appeared so frequently that it was difficult to
4 not infer that this might be the --
5 (Telephone interference)
6 CHAIRMAN MALMUD: Shall we move on? Pat?
7 MEMBER ZANZONICO: Yes, I think we can move
8 on. So I think Item 2-C is now moot, in that the language
9 referring to attestation of competency actually does not
10 appear in the proposed rule.
11 CHAIRMAN MALMUD: Thank you. That's an
12 enormous accomplishment. Because we've been struggling
13 with this, NRC's been struggling with this with us, for
14 a long time. And that alone is quite an accomplishment.
15 MEMBER ZANZONICO: Yes, agreed.
16 CHAIRMAN MALMUD: And we thank the NRC staff
17 as well the wisdom of the ACMUI members. All right, then
18 we move on.
19 MEMBER LANGHORST: Dr. Malmud, this is Sue
20 Langhorst.
21 CHAIRMAN MALMUD: Yes, Doctor Langhorst.
22 MEMBER LANGHORST: I think maybe we should
23 just vote to make sure that we are taking that out.
24 CHAIRMAN MALMUD: All right. Is that a
25 motion, Doctor Langhorst?

1 MEMBER LANGHORST: Yes, it is.

2 CHAIRMAN MALMUD: Is it seconded?

3 MEMBER MATTMULLER: It's Steve Mattmuller.

4 Yes, second.

5 CHAIRMAN MALMUD: Thank you. Any further

6 discussion of the item?

7 MEMBER GUIBERTEAU: Doctor Malmud?

8 CHAIRMAN MALMUD: Yes, who is this?

9 MEMBER GUIBERTEAU: This is Mickey

10 Guiberteau. I'm sorry, I just got back --

11 CHAIRMAN MALMUD: Yes, Mr. Guiberteau.

12 MEMBER GUIBERTEAU: -- back on the call. I

13 hear that we're taking this out. I just wanted to make

14 certain that the sub-committee is, the word competency,

15 as has been said, has always been an issue.

16 But the statement that was read from the

17 rule, and the statement that is here proposed is a bit

18 different in that the proposed rule really indicates that

19 there should be an attestation that the trainee has

20 fulfilled the T&E requirements, and is able to function

21 independently in the position for the authorization.

22 So there is still a judgment involved, as

23 opposed to the language here, which simply says that the

24 training has been fulfilled, and that training is

25 consistent with achieving a level, an ability.

1 So I realize it's small, but there may be
2 some who feel like making any sort of judgment regarding
3 a trainee, as to how they may perform in practice, is not
4 acceptable. And I just want to point that out before you
5 eliminate this.
6 CHAIRMAN MALMUD: If you take a look at Page
7 99, lines 2927 through 2930, are those lines acceptable
8 to you, Doctor Guiberteau?
9 MEMBER GUIBERTEAU: They're acceptable to
10 me. And to be honest, I think they're fine. But I'm
11 just pointing out that there is a difference that what
12 is read, and I don't have that in front of me
13 unfortunately. I'm not in a location where --
14 CHAIRMAN MALMUD: Oh, I'll read it to you
15 if I may.
16 MEMBER GUIBERTEAU: All right, right.
17 CHAIRMAN MALMUD: "Has obtained written
18 attestation, signed by a preceptor authorized, in this
19 case nuclear pharmacist, that the individual has
20 satisfactorily completed the requirements in Paragraph
21 D-1 of this section, and is able to independently fulfill
22 the radiation safety related duties as an authorized
23 nuclear pharmacist."
24 MEMBER GUIBERTEAU: Right. Personally, I
25 have no issue with it. I'm only pointing out that there

1 is a judgment as to whether a person is able to do the
2 job, as opposed to what the statement that the
3 sub-committee has written, which said that the training
4 has been achieved, and that training is consistent with
5 an ability, but doesn't require a judgment.
6 And I'm just saying that in the past there
7 was the issue of judging competency. In this case, it's
8 judging an ability. And if we're fine with that, then
9 I personally am fine with that.
10 But I do know that there have been some
11 objections to a judgment of any sort on the part of future
12 performance by a trainee by some of the authorized users
13 who provide these statements. So I just want to make
14 sure that everyone is clear on that before we move on.
15 CHAIRMAN MALMUD: Yes, I understand your
16 concern, Doctor Guiberteau. Are there others who wish
17 to comment about this?
18 MEMBER ZANZONICO: This is Pat Zanzonico.
19 I think the point is well taken. And the intent in my
20 suggested language was to eliminate entirely the
21 judgment call.
22 So if we amended this language, made a
23 recommendation to amend this language, say in Line 2929
24 and elsewhere, and change "and is able to independently
25 fulfill," change that, consistent with being able to

1 independently fulfill, or consistent with the ability to
2 independently fulfill, et cetera. That would seem to
3 eliminate any judgment call.
4 MEMBER GUIBERTEAU: Dr. Malmud?
5 CHAIRMAN MALMUD: Yes.
6 MEMBER GUIBERTEAU: This is Mickey
7 Guiberteau.
8 CHAIRMAN MALMUD: Yes.
9 MEMBER GUIBERTEAU: I think that language
10 that has been proposed, quite frankly, is excellent, by
11 the sub-committee. And I think it would be acceptable
12 to a broader group of authorized users who are serving
13 as preceptors. And so I would support that.
14 CHAIRMAN MALMUD: You would support the
15 current language, Doctor Guiberteau?
16 MEMBER GUIBERTEAU: No. Although I
17 personally don't have any issue with the proposed rule,
18 I do think that the language proposed by the
19 sub-committee is preferable to a wider spectrum of
20 authorized users acting as preceptors for trainings. And
21 so personally I would support the language proposed by
22 the sub-committee, as an ACMUI member.
23 CHAIRMAN MALMUD: All right. So we have a
24 comment from Doctor Guiberteau, a member of the ACMUI,
25 that the other language is preferable to that which is

1 in Line 2828 and 2829, specifically 2929. Dr. Zanzonico?
2 MEMBER ZANZONICO: Well, let me just
3 reiterate then what that language is. The language
4 would be, "Has satisfactorily fulfilled the training and
5 experience requirements consistent with achieving a
6 level of competency sufficient to function independently
7 in the position for which authorization is sought."
8 And the key distinction in that language is
9 the preceptor is simply attesting to achieving training
10 and experience consistent with. So there's no judgment
11 call at all.
12 I think that's preferable. I think the
13 language which most decisively eliminates the judgment
14 call on the part of the preceptor is preferred.
15 CHAIRMAN MALMUD: You have re-entered the
16 word competency, though.
17 MEMBER ZANZONICO: Well, good point. Yes.
18 MEMBER GUIBERTEAU: This is Mickey
19 Guiberteau. I think the word competency is also a loaded
20 term that many authorized users acting as preceptors are
21 uncomfortable with.
22 I totally agree with their position. I do
23 think that the language that the sub-committee has
24 proposed, that if we use the language that you had amended
25 that language to a moment ago, by using ability as

1 consistent with achieving an ability to act, is
2 preferable to competency.
3 MEMBER ZANZONICO: Right, I agree, I agree.
4 MEMBER LANGHORST: Doctor Malmud, this is
5 Sue Langhorst.
6 CHAIRMAN MALMUD: Doctor Langhorst, yes.
7 MEMBER LANGHORST: Based on this discussion,
8 I will remove my motion to remove this paragraph, I guess.
9 CHAIRMAN MALMUD: You want to remove the
10 paragraph beginning on Line 2927, which relates to the
11 nuclear pharmacists?
12 MEMBER LANGHORST: I'm sorry, no. We're
13 talking about this paragraph 2-C, where I had made motion
14 to remove that paragraph. And so I was wanting to remove
15 my motion because it sounds like we want to keep the
16 paragraph and modify the language.
17 MEMBER ZANZONICO: Can I offer the
18 re-revised language, based on Doctor Guiberteau's
19 comment?
20 CHAIRMAN MALMUD: Please do, Doctor
21 Zanzonico.
22 MEMBER ZANZONICO: Okay. It would be, "Has
23 satisfactorily fulfilled the training and experience
24 requirements consistent with being able to independently
25 function in the position for which authorization is

1 sought."

2 CHAIRMAN MALMUD: Is that a motion, Doctor

3 Zanzonico?

4 MEMBER ZANZONICO: Yes, let's call it a

5 motion.

6 CHAIRMAN MALMUD: Do you want to put that

7 before your sub-committee?

8 MEMBER ZANZONICO: Yes. So let me re-read

9 that. The motion would be to use the language, "Has

10 satisfactorily fulfilled the training and experience

11 requirements consistent with being able to independently

12 function in the position for which authorization is

13 sought."

14 MEMBER GUIBERTEAU: I like it.

15 MEMBER LANGHORST: This is Sue Langhorst.

16 I like it too. But I think we need to clarify that there's

17 more changes needed in that paragraph to get rid of the

18 confusion of what you thought was the language.

19 MEMBER ZANZONICO: Agreed. No, I agree. I

20 would revise our report. This was a draft report, the

21 sub-committee draft report. I will revise it at a number

22 of points, including clarifying my confusion on what I

23 thought was being proposed versus what actually is being

24 proposed.

25 VICE CHAIRMAN THOMADSEN: Pat, this is Bruce

1 Thomadsen. Could you please repeat the current motion?
2 MEMBER ZANZONICO: Okay. The current motion
3 would be to replace, in the proposed rule, to replace
4 language that states a candidate is able to independently
5 fulfill the radiation safety related duties for which
6 authorization is being sought -- again, whether it's a
7 nuclear pharmacist, authorized user, et cetera -- to
8 change that language, "Is able to independently fulfill
9 the radiation safety related duties," to "Has
10 satisfactorily fulfilled the training and experience
11 requirements consistent with the ability to
12 independently function in the position for which
13 authorization is sought."
14 VICE CHAIRMAN THOMADSEN: Thank you.
15 MS. BHALLA: Doctor Malmud?
16 CHAIRMAN MALMUD: Yes, I was just about to
17 ask you for NRC staff's opinion about this.
18 MS. BHALLA: Yes. At the ACMUI meeting held
19 in April of 2011, we discussed this very issue about the
20 specific language. So the language that we have here is
21 the one that was approved, or recommended by the ACMUI
22 at that time.
23 And we just believe that there isn't a whole
24 lot of different words being proposed now. So just
25 wanted to say that what we have right now is what was

1 approved by the ACMUI back in April of 2011.

2 CHAIRMAN MALMUD: Yes, this is Malmud. I have

3 the same recollection as you do. You have the advantage

4 as well of having the minutes of that meeting. And we

5 struggled with it at that time.

6 And we had hoped that the NRC would be

7 willing to accept terminology that eliminated the word

8 consistent. And we achieved that in the wording that you

9 have in the current document.

10 I truly don't see much difference in what

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

12 Because if the concern is that someone may be sued for

13 the actions of his or her trainee some years later, I

14 don't see a difference between the wording that was

15 proposed and the wording that's in here.

16 But this is just one man's opinion. And the

17 wording of consistent with being able to independently,

18 and being able to independently function, isn't much of

19 a difference to me.

20 When we train people, we recognize that not

21 only will they be learning a lot more when they're out

22 in the field than they learned during the training

23 program because of the advances that are occurring

24 constantly, but that some of the things that they were

25 trained with, that are not used frequently, are forgotten

1 or need to be re-trained.

2 So I think that the wording that's been

3 achieved in the current document represents that which

4 we worked for, for a period of several years, at least.

5 However, if the committee feels that

6 there's an improvement to be made with this, then

7 obviously we'll recognize it. Excuse me. I don't see the

8 difference between the two.

9 MEMBER WELSH: Dr. Malmud?

10 CHAIRMAN MALMUD: Yes, I hear two voices.

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

12 CHAIRMAN MALMUD: Doctor Welsh.

13 MEMBER WELSH: If I recall correctly, please

14 correct me if not accurate, it was not the word

15 consistent, but the word competence that was most

16 offensive.

17 CHAIRMAN MALMUD: You're correct, you're

18 correct. It was the word competence. That was my slip.

19 It was the word competence.

20 MEMBER WELSH: The current iteration,

21 although the words may not be exact, seems to be in the

22 correct spirit.

23 CHAIRMAN MALMUD: Yes.

24 MEMBER WELSH: It just is a matter of

25 word-smithing to make sure that we don't have the word

1 competence, which leaves us liable as preceptors, or even
2 the board as an organization, to say that this person is
3 qualified and is competent because he passed the boards.
4 That omission of the word competence is what we are
5 seeking today.
6 CHAIRMAN MALMUD: Yes, you are correct. I
7 mis-spoke in this last statement. I earlier said it was
8 the word competence that was the issue of conflict, and
9 it was the issue of conflict. It appears to be resolved,
10 but I think someone else wanted to make a comment as well.
11 MEMBER PALESTRO: Yes, Chris Palestro.
12 CHAIRMAN MALMUD: Yes, Doctor Palestro.
13 MEMBER PALESTRO: I have to agree with you,
14 Leon, in reading the two sections. I couldn't really
15 appreciate a difference. One may sound more palatable
16 than the other, or less intimidating. But I'm just not
17 sure that there's significant difference between the
18 two.
19 MEMBER ZANZONICO: This is Pat Zanzoniko.
20 Given this discussion, I think the language using the
21 word consistent is preferable. Having said that, I have
22 no strong objection whatsoever to the language as it's,
23 the new language, currently in the proposed rule.
24 And I would have no hesitation about asking
25 the sub-committee, and then the full committee, for a

1 vote on the language as it appears in the, the new
2 language as it appears in the proposed rule.
3 CHAIRMAN MALMUD: So is that proposal to your
4 committee that the current language as printed in the
5 document, without change, is acceptable?
6 MEMBER ZANZONICO: Yes. That would be asking
7 for a vote on that recommendation.
8 CHAIRMAN MALMUD: Does the rest of the
9 sub-committee agree with Doctor Zanzonico?
10 MEMBER PALESTRO: Yes.
11 MEMBER LANGHORST: Yes.
12 CHAIRMAN MALMUD: Any objections to it? Any
13 abstentions? So you have unanimity once again, Doctor
14 Zanzonico. Now we'll present that to the entire committee
15 and ask for their approval of the wording as it's printed
16 in the current document, an example of which is on Lines
17 2927 through 2930, for approval.
18 Anyone object? Does anyone abstain?
19 Hearing neither objection nor abstentions, we will
20 declare it unanimous. I must tell you that I have to
21 congratulate you, Doctor Zanzonico, and members of the
22 committee.
23 Because you've achieved something we've
24 been struggling with for three, if not four, years.
25 Thank you very much. We will move on to the next numbered

1 item if we may.

2 MEMBER ZANZONICO: Yes. And this was Item

3 2-D. And the issue, as I tried to state it initially,

4 seemed to be that the proposed rule was parsing, for lack

5 of a better term, authorization to use different types

6 of radionuclides and radiopharmaceuticals that is more

7 restrictive than what's in the current rule.

8 Again, in Lines 1503 to 1508 it states, "The

9 current regulations include a broad category for

10 parental administration of any other radionuclide."

11 This fourth category would be removed as any new parental

12 administration of radionuclides not listed in this

13 paragraph would be regulated under 35-1000.

14 This approach would allow the NRC to review

15 each new proposed radionuclide for parental

16 administration and determine the appropriate P&E for its

17 use.

18 Now, the NRC staff will correct me if I

19 misunderstood. But my inference is that this new proposed

20 rule would allow the NRC the latitude to review each new

21 radiopharmaceutical, or radionuclide, on a case by case

22 basis, which just seems far more onerous, potentially,

23 than the current rule, which at least has broad

24 categories of types of radionuclides. So again, I think

25 the sub-committee feels that the different classes of

1 radionuclides and radiopharmaceuticals, in terms of
2 clinical applications, radiation safety, radiation
3 biology, are far more similar than they are different,
4 and that a radionuclide by radionuclide, or
5 radiopharmaceutical by radiopharmaceutical
6 authorization is really excessive and unnecessary.
7 And so we feel that practitioners who have
8 the requisite training in engineering, and experience,
9 rather, to safely and effectively utilize any one, any
10 class of diagnostic and therapeutic radionuclides have
11 the training and experience to utilize all of them.
12 CHAIRMAN MALMUD: That's been the assumption
13 until now, that if we're competent to use a class of
14 radiopharmaceuticals, or radionuclides, that we are able
15 to handle others as they come.
16 MEMBER ZANZONICO: Right. If I could ask the
17 NRC staff, am I misunderstanding the meaning of the
18 language, of the relevant language in the proposed rule?
19 CHAIRMAN MALMUD: That's a question from
20 Doctor Zanzonico to NRC staff.
21 Dr. Howe, are you on the line?
22 DR. HOWE: Yes, I am.
23 CHAIRMAN MALMUD: Would you like to comment?
24 DR. HOWE: Okay. The intent was to break the
25 radiopharmaceuticals into basic categories, either oral

1 I-131 or --

2 COURT REPORTER: Excuse me, this is the court

3 reporter? Who is speaking, please?

4 DR. HOWE: This is Doctor Howe.

5 COURT REPORTER: What is your first name?

6 DR. HOWE: Donna-Beth.

7 COURT REPORTER: Thank you.

8 DR. HOWE: So the idea was to break it into

9 major groups, so that one group would be the oral

10 administration of I-131. And there would be two groups

11 of that, either less than 33 millicuries or greater than

12 33 millicuries.

13 Then the next category was for all

14 radiopharmaceuticals that are used primarily for their

15 photon or electron emissions.

16 So each time you got a new radionuclide, you

17 would look and see what it was being primarily used for.

18 So you would not be making a judgment on every individual

19 new radiopharmaceutical or radionuclide, as longs as it

20 fit into the category. And the fourth category was that

21 it was being used primarily for its alpha emissions. And

22 so if something is primarily used for its alpha

23 emissions, it would go into the fourth category.

24 Now, if there were some other type of

25 radionuclide that's not used primarily for its electron,

1 photon, or alpha, then that would go into the statement
2 of consideration we're talking about, that we would
3 review independently.
4 So that was the intent. So the intent is not
5 to look at each individual radionuclide and make
6 regulations for it, but just to see if it fits into one
7 of those four categories.
8 And only if it didn't fit into one of those
9 four categories, would we be making an independent
10 evaluation. Does that help clarify things?
11 MEMBER ZANZONICO: It does, thanks.
12 Another question though. So for example, would an
13 authorized user be authorized to use the individual
14 classes of radiopharmaceuticals?
15 So for example, they could be authorized to
16 use I-131 photon emitted, beta emitted, but conceivably
17 not alpha emitters.
18 DR. HOWE: That's correct. If they did not
19 have clinical experience with the alpha emitters, then
20 they would need the clinical experience with an alpha
21 emitter. And then that would be added to their category.
22 MEMBER ZANZONICO: That's where I think my
23 objection would lie. If an authorized user had the
24 necessary training and experience to use, for example,
25 I-131, or a beta emitter therapeutically, that should

1 suffice to allow them to use the alpha emitters
2 therapeutically, whether or not they had specific
3 experience with an alpha emitter.
4 This is the issue that arose, of course, in
5 connection with the radium dichloride. And so I
6 understand it's not radionuclide by radionuclide, or
7 radiopharmaceutical by radiopharmaceutical, but it is
8 type of emitter by type of emitter authorization.
9 And my personal feeling is that that's
10 excessive. I don't know what the feelings of other
11 members of the ACMUI may be.
12 VICE CHAIRMAN THOMADSEN: This is Bruce
13 Thomadsen. And as I recall, our discussion at the ACMUI
14 meeting that was, indeed, the consensus of the group.
15 MEMBER ZANZONICO: Yes. That's my
16 recollection as well. Thank you for confirming that. So
17 I think our --
18 MEMBER LANGHORST: Pat?
19 MEMBER ZANZONICO: Yes.
20 MEMBER LANGHORST: This is Sue Langhorst.
21 May I speak?
22 MEMBER ZANZONICO: Please.
23 MEMBER LANGHORST: One of the confusing
24 factors of adding a parental alpha emitter, there'll be
25 a lot of licensees who don't have that approval to use

1 that type of radiopharmaceutical.

2 So it basically negates being able to get

3 training and experience under 390. And if NRC insists on

4 having all these separate sub-categories, I would

5 recommend that the 390 be done away with, and you keep

6 only the 392, 394, 396, and then add a 398, I guess, for

7 the alpha emitters.

8 Because it gets so confusing as to who's

9 been trained on what. And I agree with Pat. If you know

10 how to administer parental radiopharmaceuticals, alpha

11 versus beta has very little difference.

12 And I don't agree with having the separate

13 Item D in that category for alpha emitters. It makes no

14 sense to me. Thank you.

15 MEMBER ZANZONICO: Thank you.

16 CHAIRMAN MALMUD:So, Pat, what do you

17 recommend at this point?

18 MEMBER ZANZONICO: Let me see if I can

19 formulate this in terms of a votable recommendation.

20 MEMBER SULEIMAN: Well, this is Orhan

21 Suleiman. Can I say something?

22 MEMBER ZANZONICO: Please.

23 MEMBER SULEIMAN: As I recall, I disagreed

24 with the majority at that meeting, because the chemical

25 form of the radio-labeled drug may cause it to behave very

1 differently.

2 And where the radioactivity winds up may

3 cause it to behave very differently. And so whether this

4 is an NRC regulatory requirement, or this is just prudent

5 practice of medicine where the physician has the

6 appropriate privileges to do something, I really have a

7 bad case for lumping everything into simple categories.

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

9 complicated procedures you have, not only with all sorts

10 of complex therapies, when you start to get into the

11 potential armamentarium for radio-labeled drugs, I don't

12 think you can micro-regulate.

13 But at the same time, I don't think

14 exempting and allowing everybody in the group to have the

15 authority to use all sorts of different radio-labeled

16 drugs is good.

17 Take it away from the Research Institute.

18 Take it away from the Memorial Sloan Kettering, or any

19 of the other places where most of you work. And go out

20 into the hinterland where you've got some users who never

21 show up at these meetings, who really just want to

22 practice medicine, and they're authorized to use a

23 certain class of radioactive drugs.

24 And along comes something that's very

25 similar. And you're going to allow them the authority to

1 start using it when they may, in fact, not have the
2 necessary training. So that's my thinking.
3 How do you protect against that? I'd like
4 to hear from our physician members. How would you ensure
5 that a physician, a nuclear medicine doctor, or a therapy
6 physician at some community hospital who's authorized to
7 use one of these other products, gets something new, and
8 how do you assure that he's got the appropriate training?
9 MEMBER LANGHORST: Sue Langhorst. I know I'm
10 not a physician, but can I take a shot?
11 CHAIRMAN MALMUD: Please do, Doctor
12 Langhorst.
13 MEMBER LANGHORST: Thank you. Orhan, there's
14 a difference between training and experience
15 requirements to become an authorized user and then the
16 license to use certain radioactive materials, and the
17 specific training that a licensee and their authorized
18 users need to have in order to utilize a new
19 radiopharmaceutical.
20 So I think what we're talking about here is
21 what is the base training and experience an authorized
22 user needs to have in order to work with the normal
23 radiopharmaceuticals, and then have enough depth of
24 knowledge that then they can apply with additional vendor
25 training on new radiopharmaceuticals, the specific

1 procedures that have to be in place, both radiation
2 safety and patient safety-wise, in order to administer
3 these new forms of radiopharmaceuticals.
4 MEMBER SULEIMAN: Orhan Suleiman. Well, if
5 that's how it plays out, that's great. But how do you
6 ensure that these individuals will exercise the proper,
7 and again, the proper professional judgment to say I
8 really need training to use this modality.
9 MEMBER ZANZONICO: And this is Pat
10 Zanzonico. Your point is well taken. But my feeling is
11 that parsing radiopharmaceuticals by the type of emission
12 doesn't address that issue.
13 There's always going to be an issue of
14 practitioner competency with any new
15 radiopharmaceutical, or in medical oncology any new drug,
16 or in surgery a new surgical procedure.
17 But in the context of clinical use of
18 radioactive materials, my point, as I said, is that
19 parsing authorization based on type of emission still
20 doesn't address that.
21 You can have very diverse beta emitters, or
22 beta emitting radiopharmaceuticals for therapy, and an
23 AU can be as competent, or incompetent, in using these
24 very different beta emitting radiopharmaceuticals, as
25 using a beta emitter versus an alpha emitter.

1 So it's not that the issue of a learning
2 curve and competency in using different agents is not a
3 real one. It's that parsing them according to radiation
4 emissions doesn't address that issue. It's an
5 artificial regulatory manipulation that really doesn't
6 serve any purpose.
7 MEMBER MATTMULLER: Dr. Malmud, this is
8 Steve Mattmuller, if I may.
9 CHAIRMAN MALMUD: Yes, Steve.
10 MEMBER MATTMULLER: First of all, I'd like
11 to agree with Orhan one important point, that I certainly
12 agree that the radiopharmaceutical chemical composition
13 is a far more challenging aspect for physicians getting
14 experience with these therapeutic radiopharmaceuticals,
15 in that the I-131 antibody effects are, Tositumomab is
16 far more challenging to use safely in a patient then, say,
17 a single dose of even radium-226 alpha radon.
18 The type of radioactive emission is really
19 inconsequential. It's the type of radiopharmaceutical
20 that can present a much greater challenge to being used
21 safely.
22 That said, I think we have to realize the
23 limitations of the NRC's regulatory reach, in that they
24 can only regulate per type of radioactive emission,
25 whether we want to go with what they suggested in

1 separating them out, or keeping them all together, as Pat
2 had suggested and Sue had suggested. And I would agree
3 with that concept also.
4 And then just to address Orhan's other
5 concern, actually the FDA, in the introduction of new
6 complex radiopharmaceuticals, it does have a training
7 program for a new user to go through, and prepare to do
8 the calculations necessary for planning the treatment.
9 And these calculations all have to be
10 reviewed and approved before they can attain an
11 independent status of using it (telephonic
12 interference). So there is some training in place for the
13 more complex radiopharmaceuticals right now. Thank you.
14 CHAIRMAN MALMUD: Thank you. We're back
15 to the issue, Dr. Zanzonico.
16 MEMBER ZANZONICO: Well, again, I don't
17 think there's disagreement that new or additional
18 training for new and potentially different and more
19 complex radiopharmaceuticals is appropriate.
20 I think where the sub-committee and the
21 ACMUI disagree with the NRC is that basing the training
22 and experience requirements on radiation emissions
23 doesn't address that, and really doesn't serve the public
24 or patients.
25 So unless there was additional comments

1 from the sub-committee or the ACMUI, or the NRC staff,
2 I would offer the following recommendation for a vote,
3 first by the sub-committee, then the committee as a whole.
4 And that is, and it's basically the last
5 sentence of Item 2-D, namely "Pracitioners who have the
6 requisite training and experience to safely and
7 effectively utilize any emitter diagnostically, and/or
8 therapeutically, have the training and experience to
9 utilize all of them. And authorization should not be
10 emission specific."
11 So what I'm asking for then, is approval by
12 the sub-committee, and then the committee as a whole, to
13 submit that recommendation to the NRC.
14 CHAIRMAN MALMUD: So you're putting the
15 motion before the sub-committee.
16 MEMBER ZANZONICO: Correct.
17 CHAIRMAN MALMUD: And you're going to poll
18 the sub-committee. All right, polling the sub-committee,
19 all in favor of this motion --
20 MEMBER WEIL: Dr. Malmud, this is --
21 CHAIRMAN MALMUD: Who's speaking please?
22 MEMBER WEIL: This is Laura Weil.
23 CHAIRMAN MALMUD: Yes?
24 MEMBER WEIL: Before we actually vote, could
25 I ask NRC staff to respond to Doctor Zanzonico's last

1 comment, and justify why they feel it might be inadequate?
2 CHAIRMAN MALMUD: Certainly you can ask.
3 NRC staff, who wishes to respond? Doctor Howe?
4 DR. HOWE: Getting off mute. When we look at
5 the radiation safety issues that are associated with
6 different radionuclides, we believe that the radiation
7 safety that's involved with photons, and then with beta
8 particles, or with alpha, are very different.
9 With radium-223 we were able to look at how
10 you measured it. And you measured it basically using the
11 photons. And so there wasn't a difference as to how you
12 could detect contamination, how you could measure what
13 you believe to be the activity of things.
14 You could use the same equipment that you
15 were using automatically already. But we do believe that
16 there's a difference in how beta particles interact, and
17 that since most nuclear medicine positions are primarily
18 photon, that there is a need for additional training for
19 some of these new emitters coming down. So that's our
20 basic reasoning. Thank you.
21 CHAIRMAN MALMUD: Does that answer your
22 question?
23 MEMBER WEIL: It does. It does and I have
24 to say that I agree with NRC staff on this.
25 MEMBER LANGHORST: Dr. Malmud, this is Sue

1 Langhorst.

2 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

3 MEMBER LANGHORST: I would like to get a

4 clarification from Dr. Zanzonico. Pat, are you saying

5 that the NRC should do away with the different levels of

6 I-131 therapy and diagnostics?

7 MEMBER ZANZONICO: No, Sue. Because I think

8 that there is a fundamental distinction between whether

9 one is using radioactivity diagnostically or

10 therapeutically.

11 If one is using it therapeutically, the

12 authorized user has a responsibility to medically manage

13 a patient who may suffer acute or deterministic effects

14 as a result, and has to have the training and experience

15 to do that properly.

16 If one is strictly using them

17 diagnostically, those classes of effects are

18 inapplicable. So I mean I think there is a fundamental

19 distinction between, or among, or between therapeutic and

20 diagnostic applications and therefore in relation to

21 administered activities.

22 But I think all authorized users, and who

23 use radioactivity clinically, have training and

24 experience in radiation physics, in radiation detection

25 and instrumentation and so forth. And understand the

capabilities and limitations of different instruments in detecting different types of radiations and so forth.

So it's not to say that there aren't valid distinctions and valid reasons for different types of required training and experience among different applications of radiopharmaceuticals or radioactivity clinically, but that basing that distinction strictly on admissions is not a valid one.

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

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

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

MEMBER ZANZONICO: Yes, that's basically correct.

MEMBER LANGHORST: Okay, I agree with that.

1 Thank you.

2 CHAIRMAN MALMUD: Just a minor correction.

3 The lower doses of I-131 below grade, ie. below 33

4 millicuries, are also therapeutic. Therefore

5 hyperthyroidism versus the ones that are 100 millicuries

6 or more which tend to be more than 50 millicuries or more

7 tend to be for thyroid cancer. MEMBER LANGHORST:

8 Thanks for correcting me Dr. Malmud. This is --

9 CHAIRMAN MALMUD: Okay, I'm sorry. But you

10 are also correct in that there are lower doses of I-131

11 in the order of 3 millicuries, which is still used in

12 remote locations were I-123 is not available for

13 diagnostic purposes. You are correct in that.

14 At any rate, getting back to the subject.

15 So Dr. Zanzonico, the ball is in your court.

16 MEMBER ZANZONICO: Well I would still, I mean

17 I appreciate the comments and the rationale offered by

18 the NRC staff, but I'm unconvinced at this point and would

19 still offer my recommendation for a vote. And I can

20 repeat it if you like?

21 CHAIRMAN MALMUD: Please repeat it.

22 MEMBER ZANZONICO: Okay. The recommendation

23 would be, or the vote would be to recommend to the NRC

24 the following:

25 "Practitioners who direct the training and

1 experience to safely and effectively utilize any
2 radiopharmaceutical, diagnostically and
3 therapeutically, have the training and experience to
4 utilize all of them and authorization therefore should
5 not be emission specific."
6 CHAIRMAN MALMUD: That is the motion.
7 VICE CHAIRMAN THOMADSEN: Okay, this is
8 Bruce Thomadsen. If I could propose an amendment? Instead
9 of all of them, any of them.
10 MEMBER ZANZONICO: Okay, agreed.
11 CHAIRMAN MALMUD: Any other amendments to
12 this motion which is being put before the subcommittee?
13 MEMBER LANGHORST: Well we have, this is Sue
14 Langhorst, so we have a chance to ask more questions?
15 CHAIRMAN MALMUD: Absolutely.
16 MEMBER LANGHORST: Can I now?
17 CHAIRMAN MALMUD: Yes you may.
18 MEMBER LANGHORST: Pat, I believe what
19 you're proposing here encompasses all of 190, 290 and 390?
20 And so I don't think I can agree with this.
21 And that's why I was trying to clarifying,
22 you're only talking 390 and are you only talking C and
23 D items or do you mean NRC should do away with 190, 290
24 and 390?
25 MEMBER ZANZONICO: I have to confess to you,

1 I'm just not as familiar off the top of my head with the
2 Sections of the Regs as you are. The gist of what I'm
3 trying to propose, and perhaps you can formulate it in
4 a much better way, but the gist of what I'm trying to
5 propose is eliminating the language, or the sections in
6 the proposed rule, which would require separate training
7 and experience based on type of emission, of radiation
8 emission.
9 MEMBER LANGHORST: And this is Sue Langhorst
10 again. So you mean between the beta emitting therapy
11 radiopharmaceuticals, beta and proton emitting versus
12 alpha emitting? Is that the --
13 MEMBER ZANZONICO: Correct.
14 MEMBER LANGHORST: Okay, so I would agree
15 with your point if that's what you're limiting it to. But
16 the wording you're using is all and any.
17 MEMBER ZANZONICO: Yes, understood. So --
18 MEMBER LANGHORST: I would recommend that
19 the motion might be that ACMUI recommends that alpha
20 emitter, parenteral-administered alpha emitting
21 radiopharmaceuticals not be separately called out for
22 training and experience, that instead the training and
23 experience should be limited to
24 parenteral-administration of radiopharmaceuticals?
25 MS. BHALLA: Dr. Malmud?

1 CHAIRMAN MALMUD: Yes.

2 MS. BHALLA: Yes, this is Neelam Bhalla

3 again, from NRC.

4 CHAIRMAN MALMUD: Yes.

5 MS. BHALLA: So for clarification, I think

6 it's important to then defer to Section 35-C-96, because

7 that's the section that pertains to the

8 parenteral-administration of radiopharmaceuticals.

9 So that would eliminate any confusion about

10 going back to 190, 290, et cetera because those sections

11 are not included in the -- again I'll talk about the user

12 need memo where the request came that right now we have,

13 under the 35-C-96, categorization of certain beta

14 emitters and then gammas up to a certain energy.

15 But there was no, I think that question came

16 up, what about alpha emitters? So the staff expressed a

17 need to create a separate category for that modality and

18 that's why this was open. So when you make your report,

19 please refer to Section 35-C-96 because that's what's

20 open to amendment.

21 CHAIRMAN MALMUD: Thank you for that.

22 DR. HOWE: Dr. Malmud?

23 CHAIRMAN MALMUD: Yes.

24 DR. HOWE: Dr. Malmud, this is Dr. Howe.

25 Actually 390 and 396 are both open because 396 pertains

1 only to the radiation oncologist, where 390 applies to
2 the nuclear medicine physicians.
3 CHAIRMAN MALMUD: Thank you for clarifying
4 that, Dr. Howe.
5 MEMBER LANGHORST: This is Sue Langhorst.
6 Dr. Howe, I disagree with that. 390 refers to any
7 physician that meets that requirement, be they radiation
8 oncologist or nuclear medicine.
9 My radiation oncologists are approved under
10 the 390, so I don't think you can clarify it in that
11 simplistic of terms.
12 DR. HOWE: Well the, this is Dr. Howe again.
13 The original intent for 396 was to allow radiation
14 oncologists that have authorized users status as
15 radiation oncologist, to use parenteral treatment
16 without having to go through the 200 hours and the other
17 requirements in 390.
18 Now I understand some of the board
19 certifications are covering both now, but if you look
20 carefully at 396, the criteria for using 396 is that your
21 are either recognized under 35-400, which is
22 brachytherapy, or in 360, which is the remote
23 afterloader, the teletheraphy and the gamma
24 stereotactics. So there is a distinction there, although
25 it's getting a little fuzzier.

1 MEMBER LANGHORST: This is Sue Langhorst. My
2 point is, is that radiation oncologist also practice
3 under 300. I mean not just that one section, but all of
4 390.
5 MEMBER WELSH: This is Jim Welsh. I fully
6 agree with what Dr. Langhorst has just said. It's part
7 of the board requirements now.
8 MEMBER LANGHORST: Dr. Malmud, this is Sue
9 Langhorst again?
10 CHAIRMAN MALMUD: Yes, Dr. Langhorst.
11 MEMBER LANGHORST: I would like to suggest
12 that maybe the subcommittee work on the wording for this
13 section a little bit in this week between our
14 teleconferences and bring forward some new language on
15 it?
16 MEMBER ZANZONICO: This is Pat Zanzonico. I
17 agree completely. I think we're in agreement on the sense
18 of what we want to express, but it will require some
19 additional discussion to formulate it properly.
20 CHAIRMAN MALMUD: Okay, that's a decision
21 which the subcommittee chair can deal with. Dr.
22 Zanzonico?
23 MEMBER ZANZONICO: Absolutely. And so we
24 would just defer this item, Item 2D to our offline
25 discussion and then pick it up again at our next

1 teleconference.

2 CHAIRMAN MALMUD: Or the next meeting.

3 MEMBER ZANZONICO: Or the next meeting.

4 CHAIRMAN MALMUD: Thank you. Is that

5 acceptable to the staff?

6 MS. BHALLA: Dr. Malmud?

7 CHAIRMAN MALMUD: Yes.

8 MS. BHALLA: We would really appreciate it

9 if it's done at the next teleconference which is scheduled

10 for next week, I suppose, to meet our schedule for the

11 rule to be taken to the commission.

12 CHAIRMAN MALMUD: Thank you. Can that date

13 be met Dr. Zanzonico?

14 MEMBER ZANZONICO: Absolutely.

15 CHAIRMAN MALMUD: Okay, you're wish is

16 subcommittee's command. Thank you. Dr. Zanzonico?

17 MEMBER ZANZONICO: Before continuing, the

18 question I have is, what the schedule is in terms of the

19 next teleconference?

20 I'm wondering at this point, since we're

21 approaching the end of the allotted time for today's

22 teleconference, if it might be more logical and more

23 productive to resume our discussion, first with this last

24 point and then go on to Item 3 and the remaining items

25 at that time as opposed to beginning a discussion of these

1 additional items at this point?

2 CHAIRMAN MALMUD: I think that's a

3 constructive suggestion. The Committee maybe facing

4 fatigue since we're approaching three hours. Is that

5 acceptable to the members of the NRC staff as well as to

6 our Committee members?

7 MS. BHALLA: Dr. Malmud, this is Neelam

8 Bhalla. Very quickly I wanted to bring one clarification

9 so that when we meet next time maybe the subcommittee can

10 take a look at that before we meet?

11 CHAIRMAN MALMUD: You want to --

12 MS. BHALLA: And that should not --

13 CHAIRMAN MALMUD: I beg your pardon?

14 MS. BHALLA: I said that should not take

15 long, it's one clarification I want to make and so that

16 when we meet next time subcommittee would have had time

17 to look at that.

18 CHAIRMAN MALMUD: All right, Dr. Zanzonico,

19 is that okay?

20 MEMBER ZANZONICO: Absolutely, no please.

21 CHAIRMAN MALMUD: Go ahead then.

22 MS. HOLIDAY: I just wanted to interject

23 really quick, this is Sophie. I believe you asked for what

24 our schedule is like and so we do have a backup

25 teleconference scheduled for next week on the 12th at the

1 same time, from 2:00 to 5:00 p.m.

2 The ACMUI was given the draft, the proposed

3 draft FRN December 21st. So our 90-day deadline to receive

4 your comments in the form of a final report would be March

5 21st.

6 So if at all possible, we would like to

7 resolve all comments and have approval or a consensus on

8 that subcommittee report by the end of next meeting?

9 MEMBER ZANZONICO: Ms. Sophie, that's our

10 intent, absolutely.

11 MS. HOLIDAY: Great, thank you.

12 CHAIRMAN MALMUD: We shall endeavor to do so

13 Sophie.

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

15 CHAIRMAN MALMUD: Dr. Zanzonico and Bhalla?

16 MEMBER ZANZONICO: Well I just wanted to hear

17 this comment related to Item 3A?

18 CHAIRMAN MALMUD: Yes.

19 DR. BHALLA: Yes. So in Item 3A, which is

20 about extending grandfathering to certain certified

21 individuals, which is the Ritenour Petition.

22 I would just bring the, it seems like when

23 you read this paragraph, especially the last line it says,

24 wouldn't they already be named on our license? This is

25 with regard to those qualified individuals.

1 It seems like it's a question and I just
2 wanted to make the clarification that the whole of the
3 Ritenour Petition was based on the fact that there were
4 certain individuals. Namely, the petitioner said, the
5 RSOs and the physicists who were not named on the
6 licensed, because 35-57 starts with these individuals who
7 were certified on an NRC license.
8 So the petition came, we said that well
9 there were people who were qualified but they were not
10 named on a license and therefore here NRC, do something
11 about it for these individuals. So I just wanted to do
12 that clarification right now, that the entire petition
13 is based on the fact these people were not licensed, were
14 not named on a license and therefore they got kind of left
15 behind or they were not grandfathered.
16 So with that clarification, maybe the
17 subcommittee would rethink as to why the importance laws
18 of that particular date be October 2005. Because that's
19 when the old Subpart J went away and these people who were
20 not named on a license, now they needed to, or right now
21 they need to meet the new requirement.
22 And therefore what we want to or how we want
23 to correct that, is to bring back all those rules. And
24 you would have seen that in the proposal. We literally
25 brought the old rules back into the Regs.

1 We didn't want to refer them to, that go back
2 to 2002 or to 2005 and go look at all the rules. So I just
3 wanted to bring that to the attention of the subcommittee
4 that the date is important and that, yes indeed, these
5 people were not listed on the license.
6 CHAIRMAN MALMUD: Thank you and --
7 MEMBER ZANZONICO: Thank you.
8 CHAIRMAN MALMUD: -- what's the proposed
9 resolution to the issue?
10 MEMBER LANGHORST: Dr. Malmud, this is Sue
11 Langhorst.
12 CHAIRMAN MALMUD: Yes Dr. Langhorst.
13 MEMBER LANGHORST: Neelam, thank you very
14 much for your clarification on that because I don't think
15 that the language in the draft proposed rule right now
16 makes that clear. And that's what we were trying to get
17 across in this point.
18 And so we will be a little more, Pat, if you
19 allow me to say this, we'll be a little more careful in
20 pointing out where we think that is not made clear in the
21 draft proposed rule that you have before us.
22 MEMBER ZANZONICO: Absolutely.
23 MS. BHALLA: And this is Neelam again. And
24 we appreciate that and we would make that clarification
25 that these were the people who were not named on the

1 license.

2 CHAIRMAN MALMUD: Thank you.

3 MEMBER ZANZONICO: That's helpful, I think

4 it will, that this will expedite the discussion of this

5 item on the next teleconference.

6 MS. BHALLA: Correct.

7 CHAIRMAN MALMUD: Thank you.

8 MS. BHALLA: Thanks.

9 CHAIRMAN MALMUD: It's about 5:05 now in

10 eastern standard time. So unless there's objection, we

11 will call an end to the meeting today, pick it up at the

12 next session which is on March the 12th at 2:00 to 5:00

13 p.m.

14 Hopefully complete all the (telephonic

15 interference) that time so that we could meet the

16 deadline, which is March 21st. Is that agreeable with

17 everyone?

18 MEMBER ZANZONICO: Yes.

19 CHAIRMAN MALMUD: Is there anything of any

20 urgency that anyone feels must be brought today up at this

21 time?

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

23 CHAIRMAN MALMUD: Yes, Sophie.

24 MS. HOLIDAY: I would like to make the

25 announcement for members of the public, if you wish to

1 participate, or if wish to call in to listen to
2 teleconference meetings on next Tuesday, please send me
3 an email and I will provide you with the bridgeline
4 information, it would be different from the one that was
5 used today.
6 CHAIRMAN MALMUD: Thank you. And I know that
7 we'll receive an email from you with regard to the
8 members' bridgeline?
9 MS. HOLIDAY: Yes, sir.
10 CHAIRMAN MALMUD: Thank you. Any other
11 issues to be brought up today? If not I want to thank
12 everyone for participating in this call today, particular
13 Dr. Zanzonico and the members of the subcommittee who've
14 done an extraordinary amount of work since we last spoke.
15 I've been following all the progress and
16 discussion via the emails. And I want to thank you all
17 again and we'll look forward to meeting again next week.
18 MEMBER ZANZONICO: Very good, thank you.
19 CHAIRMAN MALMUD: Thank you all.
20 MEMBER ZANZONICO: Bye, bye then.
21 CHAIRMAN MALMUD: Is there comment from NRC
22 staff?
23 MR. EINBERG: This is Chris Einberg. On
24 behalf of the NRC staff we want to thank the ACMUI and
25 the subcommittee for all this very hard work. I know it's

1 been quite a bit to review and so we greatly appreciate
2 all your input.
3 CHAIRMAN MALMUD: Thank you all.
4 MEMBER ZANZONICO: Okay, thank you bye, bye.
5 CHAIRMAN MALMUD: Bye.
6 MEMBER LANGHORST: Bye.
7 (Whereupon, the hearing in the
8 above-mentioned matter was adjourned at 4:53 p.m.)
9
10
11
12
13
14