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1 UNITED STATES OF AMERICA

2 NUCLEAR REGULATORY COMMISSION

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4 ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

5 + + + + +

6 TELECONFERENCE

7 + + + + +

8 TUESDAY, MARCH 12, 2013

9 The meeting convened telephonically at
10 2:00 p.m. Eastern Daylight Time, Leon S. Malmud,
11 M.D., ACMUI Chairman, presiding.

12 MEMBERS PRESENT:

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

14 BRUCE THOMADSEN, Ph.D., Vice Chair

15 DARICE G. BAILEY, Agreement State
16 Representative

17 MILTON GUIBERTEAU, M.D., Diagnostic
18 Radiologist

19 SUSAN LANGHORST, Ph.D., Radiation Safety
20 Officer

21 STEVEN MATTMULLER, Nuclear Pharmacist

22 CHRISTOPHER J. PALESTRO, M.D., Nuclear
23 Medicine Physician

24 JOHN SUH, M.D., Radiation Oncologist

25 ORHAN SULEIMAN, Ph.D., FDA Representative

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1 WILLIAM VAN DECKER, M.D., Nuclear
2 Cardiologist

3 LAURA WEIL, Patients' Rights Advocate

4 JAMES WELSH, M.D., Radiation Oncologist

5 PAT ZANZONICO, Ph.D., Nuclear Medicine
6 Physicist

7

8 NRC STAFF PRESENT:

9 BRIAN McDERMOTT, Director, Division of
10 Materials Safety and State Agreements

11 CHRISTIAN EINBERG, Designated Federal
12 Officer

13 ASHLEY COCKERHAM, Alternate Designate Federal
14 Officer, ACMUI Coordinator

15 SOPHIE HOLIDAY, Alternate ACMUI Coordinator

16 NEELAM BHALLA, FSME/DILR/RPMB

17 SUSAN CHIDAKEL, OGC/GCLR/RMR

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

19 ED LOHR, FSME/DILR/RPMB

20 DEBBIE PISKURA, FSME/DMSSA/RMSB

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

22

23 NRC REGIONAL STAFF PRESENT:

24 JACKIE COOK, Region IV

25 ROBIN ELLIOTT, Region I

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1 SARA FORSTER, Region III

2 DENNIS O'DOWD, Region III

3 LESTER TRIPP, Region I

4
5 MEMBERS OF THE PUBLIC PRESENT:

6 KEITH BROWN, University of Pennsylvania

7 SUE BUNNING, Society of Nuclear Medicine and
8 Molecular Imaging

9 DAWN EDGERTON, Council for Certification in
10 Cardiovascular Imaging

11 LYNNE FAIROBENT, AAPM

12 KAREN LANGLEY, University of Utah

13 RALPH LIETO, St. Joseph Mercy Hospital

14 ANDREW McKINLEY, American Society of Nuclear
15 Cardiology

16 MICHAEL PETERS, American College of Radiology

17 MICHAEL STEPHENS, Florida Bureau of Radiation
18 Control

19 CINDY TOMLINSON, American Society for
20 Radiation Oncology

21 MICHAEL WELLING, Virginia Department of
22 Health

23 GARY E. WILLIAMS, Department of Veteran
24 Affairs, National Health Physics
25 Program

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P R O C E E D I N G S

2:01:51 p.m.

CHAIRMAN MALMUD: Hello, everyone. This is Leon Malmud, and this is a continuation of our ACMUI teleconference which began last week, and we will continue it today. However, I would like to first introduce the member of the NRC Staff who will greet us all, Chris.

MR. EINBERG: Okay, very good. Good morning, or good afternoon.

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

My name is Chris Einberg. I am Chief of the Radioactive Materials Safety Branch, and I have been designated as the federal officer for this Advisory Committee in accordance with 10 CFR Part 7.11. Present today is the alternate Designated Federal Officer, Ashley Cockerham, coordinator for the Committee.

This is an announced meeting of the Committee. It is being held in accordance with rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory

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1 Commission.

2 This meeting is being transcribed by
3 the NRC, and it may also be transcribed or recorded
4 by others.

5 The meeting was announced in the
6 February 1st, 2012 edition of the Federal Register,
7 Volume 78, page 7465, and is a continuation of
8 teleconference meeting that was held on last
9 Tuesday, March 5th, 2013.

10 The function of the Committee is to
11 advise the Staff on issues and questions that arise
12 on the medical use of byproduct material. The
13 Committee provides counsel to the Staff but does
14 not determine or direct the actual decisions of the
15 Staff or the Commission. The NRC solicits the views
16 of the Committee and values their opinions.

17 I request that whenever possible we try
18 to reach a consensus on the procedural issues that
19 we will discuss today, but I also recognize there
20 may be a minority or dissenting opinions. If you
21 have such opinions please allow them to be read
22 into the record.

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

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1 CHAIRMAN MALMUD: Here.

2 MR. EINBERG: Dr. Bruce Thomadsen, Vice
3 Chairman, Therapy Medical Physicist.

4 VICE CHAIR THOMADSEN: Here.

5 MR. EINBERG: Ms. Darice Bailey, State
6 Government Representative.

7 MEMBER BAILEY: Here.

8 MR. EINBERG: Dr. Mickey Guiberteau,
9 Diagnostic Radiologist.

10 MEMBER GUIBERTEAU: Here.

11 MR. EINBERG: Dr. Sue Langhorst,
12 Radiation Safety Officer.

13 MEMBER LANGHORST: Here.

14 MR. EINBERG: Mr. Steve Mattmuller,
15 Nuclear Pharmacist.

16 MEMBER MATTMULLER: Here.

17 MR. EINBERG: Dr. Christopher Palestro,
18 Nuclear Medicine Physician.

19 MEMBER PALESTRO: Here.

20 MR. EINBERG: Dr. John Suh, Radiation
21 Oncologist.

22 MEMBER SUH: Here.

23 MR. EINBERG: Dr. Orhan Suleiman, FDA
24 Representative.

25 MEMBER SULEIMAN: Here.

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1 MR. EINBERG: Dr. William Van Decker,
2 Nuclear Cardiologist. Dr. William Van Decker,
3 Nuclear Cardiologist? Okay.

4 Ms. Laura Weil, Patient's Rights
5 Advocate.

6 MEMBER WEIL: Here.

7 MR. EINBERG: Dr. Jim Welsh, Radiation
8 Oncologist. Dr. Welsh, are you on the line?

9 No, moving on. Dr. Pat Zanzonico,
10 Nuclear Medicine Physicist.

11 MEMBER ZANZONICO: Yes.

12 MR. EINBERG: Okay, we have a quorum. We
13 have at least seven members on the line.

14 I now ask the NRC Staff members who are
15 present to identify themselves.

16 MS. HOLIDAY: Sophie Holiday, FSME.

17 MR. WHITE: Duncan White. I'm the Branch
18 Chief for the Agreement State Program Branch in
19 FSME.

20 DR. HOWE: Donna-Beth Howe, FSME.

21 MS. BHALLA: Neelam Bhalla, FSME.

22 MS. CHIDAKEL: Susan Chidakel, OGC.

23 MR. EINBERG: Okay. For the people that
24 are on the line from Headquarters can you please
25 identify yourselves.

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1 DR. ZELAC: Ronald ZELAC, FSME.

2 MR. EINBERG: Could you repeat that for
3 the court reporter?

4 DR. ZELAC: Ronald ZELAC, FSME.

5 MR. EINBERG: Thank you.

6 MS. PISKURA: Debbie Piskura, FSME.

7 MS. COCKERHAM: Ashley Cockerham, FSME.

8 MR. EINBERG: Okay. We were just joined
9 by Ed Lohr also here in Headquarters. Now, I'd like
10 to go to the regions. Region I, who do we have on
11 the line?

12 MS. ELLIOTT: Robin Elliott, Region I,
13 DNMS.

14 MR. TRIPP: Lester Tripp, DNMS.

15 MR. EINBERG: Anybody else from Region
16 I? Okay, now I'd like to go to Region III. Is there
17 anybody on the line?

18 MS. FORSTER: Sara Forster.

19 MR. EINBERG: Okay. Can you please
20 repeat that?

21 MS. FORSTER: Sara Forster.

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

23 MR. EINBERG: Okay, Region IV now, who's
24 on the line? Anybody from Region IV? Okay.

25 Next I'd like to identify members of

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1 the public who notified us that they would be
2 participating on the teleconference. When I call
3 your name please answer that you're present. Keith
4 Brown, University of Pennsylvania.

5 MR. BROWN: Here.

6 MR. EINBERG: Sue Bunning, Society of
7 Nuclear Medicine and Molecular Imaging.

8 MS. BUNNING: Here.

9 MR. EINBERG: William Davidson,
10 University of Pennsylvania. Casey Deitrich, CQ
11 Transcriptions. Dawn Edgerton, Council for
12 Certification in Cardiovascular Imaging.

13 MS. EDGERTON: Here.

14 MR. EINBERG: Lynne Fairbent, American
15 Association of Physicists in Medicine.

16 MS. FAIROBENT: Here.

17 MR. EINBERG: Norman LaFrance, Jubilant
18 Draxlimage, Incorporated. Karen Langley, University
19 of Utah.

20 MS. LANGLEY: Present.

21 MR. EINBERG: Ralph Lieto, St. Joseph
22 Mercy Hospital.

23 MR. LIETO: Present.

24 MR. EINBERG: Magali Lurquin, Jubilant
25 Draxlimage. Andy McKinley, American Society of

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1 Nuclear Cardiology.

2 MR. MCKINLEY: Here.

3 MR. EINBERG: Tamara Mills, Jubilant
4 Draxlmage. Mike Peters, American College of
5 Radiology. MR. PETERS: Here.

6 MR. EINBERG: Joe Rodgers, Paragenics
7 Corporation. Gloria Romanelli, American College of
8 Radiology. Michael Sheetz, University of
9 Pittsburgh. Michael Stephens, Florida Bureau of
10 Radiation Control.

11 MR. STEPHENS: Here.

12 MR. EINBERG: Cindy Tomlinson, American
13 Society for Radiation Oncology.

14 MS. TOMLINSON: Here.

15 MR. EINBERG: Michael Welling, Virginia
16 Department of Health.

17 MR. WELLING: Here.

18 MR. EINBERG: Gary Williams, Department
19 of Veterans Affairs, National Health Physics
20 Program.

21 MR. WILLIAMS: Here.

22 MR. EINBERG: Okay, thank you. Is there
23 anyone else on the call that I did not call?

24 MR. McDERMOTT: Yes, this is Brian
25 McDermott, Director of the Division of Material

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1 Safety and State Agreements in FSME.

2 MEMBER WELSH: James Welsh with the
3 ACMUI.

4 MR. EINBERG: Okay. Thank you, Jim.

5 As you know, we have a bridge line
6 available for this call, and that phone number is
7 (888)864-0940. The pass code to access the bridge
8 line is 34081#.

9 At this time, I ask that everyone on
10 the call who is not speaking to place their phones
11 on mute. If you do not have the capability to mute
12 your phone, please press *6 to utilize the
13 conference line mute and unmute functions. I would
14 ask everyone to exercise extreme care to insure
15 that the background noise is kept to a minimum as
16 any background sounds can be very disruptive on a
17 conference call this large.

18 This is a Category I public meeting.
19 This is an open public observatory meeting, but is
20 non-participatory. Members of the public may listen
21 to the meeting. The draft proposed expanded Part 35
22 Rule is considered pre-decisional and has not been
23 transmitted to the NRC Commission for a vote. The
24 rule is anticipated to be sent to the Commission in
25 the late summer of 2013.

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

6 At this point, I would like to turn the
7 meeting back over to Dr. Malmud.

8 CHAIRMAN MALMUD: Thank you, Chris. If I
9 may, we have one item to present prior to the
10 agenda and that is a comment from Duncan White who
11 will brief us on an issue that was raised by
12 members of the Committee and which he will address
13 for us. Please, Duncan White.

14 MR. WHITE: Thank you, Dr. Malmud.
15 Again, my name is Duncan White. I am the Branch
16 Chief for the Agreement State Program Branch.

17 My Branch has -- one of its primary
18 responsibilities is to review all Agreement State
19 regulations for compatibility, and we do this for
20 all 37 Agreement States. And as part of that
21 process, we look at a wide range of regulations
22 including the medical ones and make determinations
23 if the States' regulations are compatible with NRC
24 regulations.

25 In addition to that, as part of the NRC

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1 rulemaking process, I serve as a co-chair to what's
2 called Standing Committee on Compatibility. When
3 draft rules are made available for comment, as you
4 know, they are provided to the states, and also at
5 that time our Committee also takes a look at it
6 with the objective to insure that the proposed rule
7 and the compatibility determinations made in that
8 proposed rule are consistent with the Agency's
9 Policy Statement on adequacy and compatibility. We
10 also look to ensure that it's consistent with other
11 rules and regulations that are already in existence
12 out there.

13 This group has been in place for about
14 four years now, and we've looked at a number of
15 different rules, hopefully to ensure that there's a
16 consistent application of the Policy Statement.

17 Again, as with any proposed rule, the
18 Committee had an opportunity to look at the
19 proposed rule that you're all looking at right now.
20 We met yesterday. We discussed the draft rule
21 yesterday with all five members of the Committee,
22 also Neelam Bhalla who was the Project Manager for
23 that, and Ed Lohr participated in that discussion.

24 One of the things that we did focus on
25 was the specific question that is in the proposed

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1 rule to ask about is the Compatibility Category for
2 the Section 35.3045 Report and Notification of a
3 Medical Event. Again, the draft FRN will ask, and
4 again this will be out for public comment, get
5 people's view on the compatibility with Category B,
6 or Compatibility Category C. And I think as written
7 in the proposed rule right now it provides a
8 balanced view of why maybe you think it would be a
9 B, or you think it would be Category C.

10 The Committee did discuss this at
11 length and unanimously indicated back to -- and
12 we'll be writing this in the memo. We unanimously
13 agreed that we felt it should be Compatibility
14 Category C. And the reason we came to that
15 conclusion is for a couple of different reasons.

16 For some -- for a section of the
17 regulations to be Compatibility Category B it has
18 to have significant trans-boundary implications.
19 And for Compatibility Category C it has to be --
20 the requirements for that, is has to -- that the
21 absence of the compatibility designation, if it's
22 Compatibility Category C it cannot create a gap,
23 duplication, or anything like that in the national
24 program.

25 And after our discussions with that, we

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1 felt it did not meet the definition of significant
2 trans-boundary implications, and certainly it did
3 qualify as Compatibility Category C.

4 Again, one of the things the group did
5 point out and did discuss at length is that -- made
6 it very clear, if the final rule, for example, is
7 Category C, the states would still be required to
8 report the source strength criteria to the NRC.
9 They would be required to do so. That is considered
10 part of the essential objective of that rule, and
11 the states must report that.

12 Under Category C they would have the
13 option of requiring their licensees to report the
14 dose-base criteria in addition to that, but they
15 would still be required, like NRC licensees are
16 required to report the source strength of the
17 activity-based quantity. They could also do this
18 additional one.

19 The other reason is that the important
20 aspect of the Policy Statement is to insure that
21 there's flexibility given to the states to adhere
22 to local conditions and local requirements. There
23 are -- we are aware of some states that do collect
24 information on medical events, misadministrations.
25 They call them different things with regard to

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1 collecting additional information for their -- for
2 individual states.

3 Some states have specific legal
4 requirements that they must meet. There's a state
5 law that they must adhere to, and that's why they
6 collect the information.

7 We had a similar situation in the past
8 where we had a different rule where, again, the NRC
9 changed the regulation, specifically changed the
10 compatibility requirements from Category C to
11 Category B, and the states -- it caused a great
12 deal of conflict with the states because the states
13 had existing programs in place. And when you go to
14 Category B, you basically require the states to
15 have the identical, exactly the same, and I mean
16 identical, I mean word for word exactly the same
17 requirements. And there were states that had
18 existing programs for -- it involved registration
19 of general license devices. And some states took --
20 some states eventually decided to petition the
21 NRC, and eventually that was -- about eight or nine
22 years later, it was returned to Category C.

23 Again, the Commission recognized that
24 the states need that flexibility for the local
25 situation the states were in. And, again, it wasn't

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1 a one-size fits all.

2 So, for this reason the Compatibility
3 Committee decided with regard to this particular
4 rule, again, we recognize it's a matter of
5 compatibility. They need to have -- they still need
6 to adhere to the new requirements which would be
7 activity-based. They could still have the option of
8 requiring their licensees to report the dose, but
9 they still must require to have the activity
10 information reported to us. And like any medical
11 event, some of this information must be reported to
12 the -- a medical event must be reported to the
13 Headquarters Operations Center and tracked in the
14 national database. They are required to report this
15 activity-based requirement, again, if the rule is
16 put into place and finalized, as such. They would
17 still be required to do that.

18 Again, that's what Compatibility
19 Category C would mean. Again, if it was C, they may
20 ask for the dose-base, and that's their prerogative
21 to do so. And they need to ask for additional
22 information. Again, that's their prerogative to do
23 so.

24 If it was a B, again, they would not be
25 able to collect any other information, and that may

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1 put them in conflict with their state laws, and
2 their state requirements. So, again, this was the
3 basis for the Committee's decision to endorse the
4 Compatibility Category C with regard to this.

5 Again, our recommendations will be
6 forwarded to Neelam Bhalla, and they will be part
7 of the Commission paper that will go up as well as
8 I understand the ACMUI's views, too, on that.

9 So, with that are there any questions
10 for me?

11 CHAIRMAN MALMUD: This is Dr. Malmud.
12 Are there any questions?

13 MEMBER ZANZONICO: This is Pat
14 Zanzonico. I have a question, if I may.

15 CHAIRMAN MALMUD: Please do.

16 MEMBER ZANZONICO: I gather in the past
17 rule on medical events for permanent implant brachy
18 one of the criteria was a dose differing from the
19 prescribed dose that would have resulted in an
20 effective dose of 5 rem, a normal organ dose of 50
21 rem, et cetera, et cetera.

22 If this were Compatibility C would the
23 states have the option, the Agreement States have
24 the option, for example, of retaining those dose-
25 based criteria?

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1 MR. WHITE: Yes, they could. Again, they
2 could do that. Again, what the requirement was for
3 Category C is to meet the essential objectives of
4 the rule. And, again, the essential objectives of
5 the rule is to report events that have -- that meet
6 the definition from a dose -- activity-based
7 perspective. If they choose to do additional stuff,
8 they may use to choose that 5 rem.

9 MEMBER ZANZONICO: I don't mean to speak
10 either for the Subcommittee or the ACMUI as a
11 whole, and actually I think I may have misspoken in
12 the written draft report when I said that there was
13 unanimity with respect to Cat B versus Cat C
14 recommendation. But my concern, if that's the case,
15 is that the -- to me, the point of the revised
16 criteria for MEs was to accurately, to sensitively
17 and specifically capture clinically significant
18 medical events in permanent implant brachy. And
19 with a Cat C specification, if these additional
20 dose criteria can still be -- can still remain in
21 effect, it seems to be undermining that key
22 objective of sensitively and specifically capturing
23 clinically significant events.

24 I think the ACMUI Subcommittee on
25 criteria for permanent implant brachy medical

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1 events went through a lot of time and effort to
2 craft a set of criteria that met that objective.
3 And if States can individually superimpose
4 additional criteria, it just seems to undermine
5 that entire objective. And I think that's the
6 underlying rationale of the majority of the ACMUI
7 in recommending a Cat B specification for this --
8 for the ME definition.

9 MEMBER WELSH: This is Dr. Welsh, if I
10 might contribute.

11 CHAIRMAN MALMUD: Please do.

12 MEMBER WELSH: Yes, I would agree with
13 what Dr. Zanzonico has just stated, that
14 Compatibility C wherein States are still allowed to
15 impose what the Subcommittee feels were
16 inappropriate criteria for medical events would
17 seriously undermine many years of very intensive
18 hard work that has been done to communicate to the
19 NRC at the very highest levels the
20 inappropriateness of the previous definitions. And
21 the key point regarding the inappropriateness of
22 the previous definitions was the use of dose as
23 criteria. And, therefore, it just does not seem to
24 make sense that what has been almost conclusively
25 and unanimously felt to be an inappropriate medical

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1 event definition, i.e., use of dose as a criteria,
2 should really not be permitted anymore because that
3 does go back to the use of clinically irrelevant or
4 clinically inappropriate definitions for medical
5 events. And we would not have gained a whole lot
6 after all this time and effort if the states were
7 to continue to use dose inappropriately as
8 Compatibility C might enable.

9 VICE CHAIR THOMADSEN: Dr. Malmud.

10 CHAIRMAN MALMUD: Yes.

11 VICE CHAIR THOMADSEN: This is Bruce
12 Thomadsen, if I may comment.

13 CHAIRMAN MALMUD: Please do.

14 VICE CHAIR THOMADSEN: One other -- one
15 reason that making this a Category C would be a
16 problem is that it's very likely to set up two
17 tiers of quality in medicine, and the states that
18 may keep the dose-based medical events criteria,
19 practitioners who would practice defensively might
20 indeed compromise what they do to definitely avoid
21 the medical events even though that also may
22 compromise their ability to treat the patients, as
23 well, compared with States that have abandoned
24 that.

25 This also would make training very

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1 difficult on a national level, and much of the
2 training for brachytherapy is nationally run, in
3 which case there would have to be two completely
4 different sets of training to make sure that the
5 practitioners would know what their medical events
6 categories would be, and how to defensively
7 practice not to violate those from State to State.
8 And in a national training course, this would add
9 difficulty.

10 We heard during the stakeholders'
11 meetings of the problems that the current
12 definition has caused in the disciplines, and
13 having part of the country maintain the previous
14 problematic definition, and part of the country
15 not, is certainly going to add confusion in the
16 field. And that cannot be good for patient care.

17 CHAIRMAN MALMUD: Thank you. Are there
18 responses to that comment from Dr. Thomadsen?

19 MR. WHITE: Again, from our -- this is
20 Duncan White. With regard to the comments, again,
21 our focus was really looking at, you know, is there
22 a -- for Category B is there specific trans-
23 boundary. And, again, we weigh that in terms of a
24 national program. We do recognize that the states
25 are still going to have to require them to provide

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1 that information. And from a practical standpoint,
2 again, I think a lot of States would go over to
3 what the NRC would have. Some would have -- I would
4 honestly say would probably have -- may have a two-
5 tier system. That's very possible, and I can't deny
6 that would not happen. Again, it's hard to predict
7 with 37 Agreement States exactly what path all of
8 them would take.

9 But, again, one thing we focused on is,
10 you know, health and safety aspect of the rule.
11 Again, we don't -- that's what we really focused
12 on. And, again, we came to the conclusion that,
13 again, it would be better served as Category C in
14 that respect. Again, we're very sensitive to the
15 fact that States may have to meet other, again,
16 requirements. Again, it's not -- I certainly
17 appreciate the comments about this should be
18 clinically significant, two-tier system. I
19 certainly appreciate that, and those are very good
20 points. Again, what we are very sensitive to is
21 that there is other -- we recognize other statutory
22 requirements in the States that they must meet, so
23 that was part of our basis for the recommendation.

24 I'm also -- I think it's -- in fact,
25 it's a question that's in there, and public input

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1 on that I think will be very good, and very, very
2 helpful just to hear -- get a full airing of this
3 discussion. I think that would be very, very good.

4 VICE CHAIR THOMADSEN: This is Bruce
5 Thomadsen. May I ask another question of the --

6 CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

7 VICE CHAIR THOMADSEN: Are there any
8 other parts of the Part 35 change that may require
9 a state to change its State regulations, its laws?

10 CHAIRMAN MALMUD: That's a question for
11 anyone on the conference call.

12 MEMBER BAILEY: That would be very --
13 this is Darice Bailey, the Agreement States' Rep.
14 That would be very difficult say not knowing all
15 the State laws. An example of what Duncan mentioned
16 regarding State laws that doesn't relate to this at
17 all. Texas has a law that we have licensed medical
18 physicists and that supposedly is a problem with
19 NRC, but it's a law, it's not a rule. So, we have
20 to live with that law. So, there may be similar
21 type situations that make these very difficult. I
22 cannot answer regarding 35 right now in any
23 particular State.

24 CHAIRMAN MALMUD: Thank you. Are there
25 other comments?

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1 MR. WHITE: Dr. Malmud, this is Duncan
2 White. I'd like to make one more comment about the
3 previous question.

4 CHAIRMAN MALMUD: Yes.

5 MR. WHITE: I know there's another State
6 that, for example, requires -- does not allow
7 reporting of specific information about the
8 location of a particular medical event, details
9 about that. Again, it's a State law, so when we do
10 get the reports from this particular state, there's
11 no hospital listed. The entries are not listed
12 because, again, State law prohibits the department
13 there from providing that information.

14 Again, it's not directly -- it's
15 tangentially related to this rule but, again, it's
16 another example of individual state requirements
17 out there that do -- that they have to adhere to.
18 And, again, we can't ask the states to break their
19 own laws, basically, to do that.

20 And to answer the question, again, I
21 don't have a specific knowledge of any other areas
22 of regulation that may be in conflict with those
23 state laws. I don't know of anything specifically
24 but, again, we do what we do. Periodically, we do
25 run into some periodically.

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1 CHAIRMAN MALMUD: Thank you. Further
2 comments or discussion?

3 MEMBER ZANZONICO: This is Pat
4 Zanzonico. I understand and empathize with the
5 requirement of the NRC not to promulgate rules and
6 regulations that might violate state laws, but
7 isn't that always a possibility? It would seem to
8 make the Cat B Category specification moot because
9 it would seem that any rule promulgated by the NRC
10 conceivably might be counter to a given State's
11 law, so how can -- in any instance, the NRB is sure
12 that that's not the case, unless it's based on a
13 state-by-state review of each and every rule and
14 its compatibility or lack of incompatibility with
15 state laws. And if that's not done it seems to make
16 the Cat B specification almost irrelevant.

17 CHAIRMAN MALMUD: Dr. Zanzonico's
18 comment is quite insightful. Is there a comment
19 from NRC Staff? The implication is that if any
20 State has a law that it would dictate to NRC what
21 NRC can do and, in fact, could affect the
22 regulations in all the states.

23 MR. WHITE: This is Duncan White, again.
24 There have been occasions where the NRC Commission
25 has approved rules and regulations which may run

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1 counter to existing state laws or state
2 regulations, and they are required -- they will be
3 required to change them. That has happened in the
4 past. Again, the Commission once it votes and
5 approves the final rule with the final
6 Compatibility determination, that's the final
7 determination and we go forward from that. And,
8 again, pending a petition or some other mechanism
9 to change the rules, the states are to find a way
10 to comply with the Compatibility Category. And if
11 that means changing law, that means changing law.

12 CHAIRMAN MALMUD: Thank you for
13 clarifying that for us. Other comments? If not, may
14 we move on having covered the subject that Duncan
15 White presented to us?

16 MR. WHITE: Thank you, Dr. Malmud, for
17 the opportunity talk to the Committee.

18 CHAIRMAN MALMUD: You're welcome. Thank
19 you for helping to clarify the issue. The issue is
20 not resolved; but it is clarified, and we
21 appreciate the clarification.

22 MEMBER ZANZONICO: Dr. Malmud, this is
23 Pat Zanzonico again. I know there was a sort of a
24 preamble so to speak to the actual teleconference,
25 but would it be appropriate at this point to either

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1 have a vote or re-vote on the recommendation with
2 regard to Cat B versus Cat C as it currently
3 appears in our draft report?

4 CHAIRMAN MALMUD: If someone wishes to
5 make the motion, we can move on it for a vote.

6 MEMBER ZANZONICO: Well, if I may, I
7 would like to make the motion so that we can move
8 past this issue on to the subsequent issues.

9 CHAIRMAN MALMUD: The Chair welcomes
10 your making such a motion.

11 VICE CHAIR THOMADSEN: And this Bruce
12 Thomadsen. I will second that.

13 CHAIRMAN MALMUD: There has been a
14 motion moved and seconded. Is the motion clear to
15 those who are on the conference call?

16 MEMBER LANGHORST: Dr. Malmud, this is
17 Sue Langhorst. No, I don't know what the motion is.

18 CHAIRMAN MALMUD: Thank you, Dr.
19 Langhorst. We will ask to have the motion repeated.

20 MEMBER ZANZONICO: This is Pat
21 Zanzonico. I can read it. And the motion is that
22 the ACMUI recommends that the draft rule redefining
23 medical events in permanent implant brachytherapy
24 be designated as Compatibility Category B.

25 MEMBER LANGHORST: Thank you. This is

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1 Sue Langhorst. It's clear now.

2 CHAIRMAN MALMUD: Thank you, Dr.
3 Zanzonico and Dr. Langhorst. Other -- is there
4 anyone else who requires clarification of the
5 motion? If not, is there a discussion of the
6 motion?

7 (No response.)

8 CHAIRMAN MALMUD: Hearing no further
9 discussion, all those in favor please say aye.

10 (Chorus of ayes.)

11 CHAIRMAN MALMUD: Are there any opposed?

12 MEMBER BAILEY: Yes.

13 CHAIRMAN MALMUD: Dr. Langhorst, is that
14 you?

15 MEMBER BAILEY: Darice Bailey.

16 CHAIRMAN MALMUD: Oh, thank you.

17 MEMBER BAILEY: Thank you.

18 CHAIRMAN MALMUD: One opposed. Any
19 abstentions?

20 MEMBER GUIBERTEAU: Yes, this is Mickey
21 Guiberteau. I abstain.

22 CHAIRMAN MALMUD: And Dr. Guiberteau
23 abstains; otherwise, the motion carries. So, the
24 motion carries with one abstention and one negative
25 vote. Both from Texas, I assume.

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1 MEMBER GUIBERTEAU: I guess that's
2 right.

3 CHAIRMAN MALMUD: You truly are the Lone
4 Star State. Thank you, and thank you, again, Duncan
5 White, for your presentation.

6 That being the case, we'll move on to
7 the agenda, and the agenda belongs to a very
8 hardworking Chairman of the Subcommittee, Dr.
9 Zanzonico.

10 MEMBER ZANZONICO: Okay, thank you very
11 much. And I also have to acknowledge all of the
12 time and effort of my fellow Subcommittee members,
13 and other members of the ACMUI. There's been a lot
14 of give and take, and really a lot of thoughtful
15 discussion and exchanges among the members of the
16 Subcommittee and the ACMUI as a whole. And I think
17 we can all be proud of our effort.

18 We had covered from our draft report,
19 and since last week's teleconference a second draft
20 has been generated based on the teleconference, and
21 based on subsequent exchanges. And the in-progress
22 as I call it second draft was circulated to all the
23 members of the ACMUI and earlier today to the NRC.
24 And we had basically addressed up to this point the
25 first three items in our draft report, the medical

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1 event definition for permanent implant
2 brachytherapy, the training and experience
3 requirements for Authorized Users and other
4 authorized professionals, and the extending
5 grandfathering to certain certified individuals per
6 the Ritenour petition.

7 So, those three issues, as I say, had
8 been addressed and we had votes on the motions and
9 so forth. Unless anyone has a need or desire to
10 revisit those issues, I would move on to the next
11 item in our draft, Item 4, which has to do with
12 measuring molybdenum contamination in generators.
13 But before I do that, is there any further comment
14 or discussion of any of the first three items?

15 MEMBER LANGHORST: Dr. Malmud, this is
16 Sue Langhorst.

17 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

18 MEMBER LANGHORST: I think, Pat, that we
19 were finishing up Item 2D and hadn't gotten to 3
20 yet.

21 MEMBER ZANZONICO: Is that correct?
22 Okay, I guess I was too optimistic.

23 MEMBER LANGHORST: Sorry about that.

24 MEMBER ZANZONICO: No, thank you for
25 correcting me. And you are right, you are correct.

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1 And I should have recollected that from our most
2 recent emails. So, let me return then to Item 2D.

3 This has to do with the training and
4 experience requirements for different classes of
5 radionuclides or radiopharmaceuticals based on
6 their radiation emissions. And in the proposed
7 rule, it's proposed to include a category for
8 alpha-emitting radiopharmaceuticals as well as beta
9 gamma emitters. And my feeling and the feeling of
10 others, though not necessarily everyone on the
11 Subcommittee as well as the ACMUI was that that was
12 not necessary or desirable, specifically that an
13 Authorized User who has the requisite training and
14 experience to use beta and gamma emitters
15 therapeutically already has the appropriate
16 training and experience to use alpha emitters, as
17 well. And there was no significant difference in
18 these different kinds of decay properties to
19 warrant this kind of parsing of authorization.

20 And then there was some -- there's been
21 continued discussion by email among the members of
22 the Subcommittee and the ACMUI, but one analogy
23 that came to mind as I was discussing with some of
24 my fellow Subcommittee members was in the field of
25 medical oncology where medical oncologists are --

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1 many medical oncologists are sub-boarded as I
2 understand in that specialty, and in that case a
3 medical oncologist can and likely would use a wide
4 variety of anti-cancer drugs which have very, very
5 different mechanisms of action, very different
6 organ toxicities and so forth; yet, being qualified
7 to perform chemotherapy-based treatment of cancer,
8 they have the necessary training and experience to
9 do that across all anti-cancer agents. And I think
10 that's actually a fair analogy, a good analogy to
11 using say alpha emitters therapeutically versus
12 gamma beta emitters therapeutically versus auger
13 electron emitters therapeutically. That's not to
14 say they might not need additional training on a
15 specific radiopharmaceutical but yet they have the
16 basic body of knowledge to be able to integrate a
17 new radiopharmaceutical regardless of its decay
18 properties into their practice, into their
19 management of patients; just as a medical
20 oncologist might require additional training with a
21 new anti-cancer agent, but yet they have the basic
22 underlying training and experience to safely and
23 effectively incorporate that into their practice.

24 So, on that basis among other
25 considerations I personally -- my personal

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1 recommendation would be that this introduction of a
2 new category of Authorized User, in effect, based
3 on alpha emission is really unnecessary,
4 unwarranted, and so forth. And with that, I would
5 open this point up for discussion by the members of
6 the Committee.

7 CHAIRMAN MALMUD: Thank you, Dr.
8 Zanzonico. MEMBER WEIL: This is Laura
9 Weil. Can I make a comment related to Dr.
10 Zanzonico's statement?

11 CHAIRMAN MALMUD: Certainly.

12 MEMBER WEIL: So, if a purpose of
13 regulation is public protection, I think we can all
14 agree that that is the case. At present it might be
15 sensible to include radium-223 since that's the
16 case in point we're after here with a larger group
17 of radionuclides for licensing purposes. But I'm
18 posing the possibility that future use of not yet
19 identified alpha-emitting radiopharmaceuticals with
20 characteristics that are very different from
21 radium-223, those other alpha emitters might need
22 different equipment skills and knowledge. And alpha
23 emitters are different enough, they have different
24 radio biology, they have different contamination
25 concerns. They need to be managed differently

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1 enough to, I believe, require different
2 authorizations.

3 And I'm not sure that I agree with Dr.
4 Zanzonico's analogy between chemotherapeutic
5 agents, in general, and radionuclides because
6 there's a difference in worker and public exposure
7 to chemotherapeutic agents than there is to
8 radionuclides in the instances of mishaps, spills,
9 or other kinds of errors, if you will. So, I'm not
10 buying the idea that we should go ahead and just
11 lump everything together into one kind of
12 authorization. I think that for protection and
13 safety purposes, it makes sense to have different
14 categories of emitters.

15 VICE CHAIR THOMADSEN: Dr. Malmud.

16 CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

17 VICE CHAIR THOMADSEN: May I comment on
18 that?

19 CHAIRMAN MALMUD: Please do.

20 VICE CHAIR THOMADSEN: If we look at
21 possible alpha emitters we really do not see any
22 isotopes that are going to behave very differently
23 than the radium-223. They just do not exist as
24 possibilities for radiotherapy treatment.

25 As we look at the current isotopes that

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1 are being used in their clinical forms, we see that
2 biologically the colloidal P-32 is very different
3 than intravascular P-32 for polycythemia vera. They
4 just are biologically completely different animals.

5 If we look at the betas from the P-32
6 and compare them with the betas from any OJ
7 emitter, biologically they're incredibly different.
8 Their relative biological effectiveness are
9 incredibly different also. As we look at the
10 radioimmune carriers in which we would put any of
11 these radio isotopes and compare their biology with
12 the IVP-32, it's incredibly different.

13 All the time we're looking at these
14 radiopharmaceuticals, each one is very different
15 and unique in its own right. That's why it exists.
16 That is part of what learning in the residency how
17 to adapt to these types of differences is very
18 important in the training, but looking at the
19 potential for the alpha emitters that much
20 difference is no greater than the difference
21 between all the existing radionuclides.

22 CHAIRMAN MALMUD: Thank you, Dr.
23 Thomadsen. Ms. Weil, does that reassure you at
24 all?

25 MEMBER WEIL: Reassuring is perhaps not

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1 the right word. Perhaps I might say then that
2 categorization by class of emitter is less than
3 perfect, but I'm having difficulty with the blanket
4 licensure for all Authorized Users.

5 MEMBER SULEIMAN: Dr. Malmud, this is
6 Orhan Suleiman.

7 CHAIRMAN MALMUD: Yes, Dr. Suleiman.

8 MEMBER SULEIMAN: Okay. Laura, don't
9 feel bad because I've always been conflicted about
10 this. You have to understand that there are two
11 different regulatory authorities or professional
12 groups of responsibility. One is the handling of
13 the radioactive materials, so the general feeling,
14 and I sort of tend more to that, is that as long as
15 the practitioner, the Authorized User understands
16 the radiation safety aspects and knows how to
17 handle these, in terms of the worker, in terms of
18 good practice, it ought to be sufficient. So, I
19 also don't really see a big difference in terms of
20 the different particulates or photons; though,
21 clearly, clearly how these behave in the body, how
22 their -- the actual chemical, the radio label
23 chemical may behave very different chemically
24 biologically, but in terms of outside the body,
25 that should be more than adequately covered by

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1 appropriate vendor training.

2 Now, getting away from the radiation
3 safety aspect, you've got the whole medical issue.
4 These are specialists, these are physicians trained
5 with this specific drug, for this specific
6 treatment, and that really comes under the medical
7 authority to practice medicine. And we have to
8 trust that the medical community is insuring that
9 these procedures are being used properly, so I --
10 the NRC can't really cover all of those other
11 issues. Those come under just the ethical practice
12 of this radio labeled therapy. So, although
13 conflicted because you're always going to have
14 examples of all sorts of things, I think sometimes
15 simplifying, continuing to generate more and more
16 subcategories to me in the bigger picture continues
17 to cause confusion. So, I would be supportive of
18 the proposal.

19 MEMBER WELSH: This is Dr. Welsh, Jim
20 Welsh, if I might comment, also?

21 CHAIRMAN MALMUD: Yes, Dr. Welsh.

22 MEMBER WELSH: So, what I've heard from
23 Laura, a statement that alpha emitters might have
24 very different biology from auger electron emitters
25 or beta emitters, and this is true. There could be

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1 differences in the radio biology. There is no doubt
2 about it. There could be differences in clinical
3 uses or clinical outcomes, as Bruce Thomadsen has
4 pointed out with the P-32 colloidal versus
5 intravenous for different applications. Same radio
6 isotope, very, very different clinical outcome
7 because of a slight difference in the chemical
8 formulation, colloidal versus -- for example. And
9 Dr. Zanzonico has pointed out an analogy with
10 chemotherapy that initially I wasn't so sure about
11 it, but I am board certified as a neural oncologist
12 and do prescribe chemotherapy. And the more I
13 thought about his statement the more apropos I
14 think his assertion is.

15 Therefore, although there are some
16 differences in biology and differences clinically
17 for different isotopes and different chemical
18 formulations of the same isotope, the overall
19 radiation safety aspects are similar, and the
20 overall radiation safety aspects, which is the
21 question at hand if I understand from Laura are
22 similar enough that the overall training and
23 experience that an Authorized User has received for
24 one should suffice for all, even though we
25 understand that there are subtle differences in the

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1 clinical outcomes and clinical applications, and
2 subtle differences in the biology, sometimes
3 they're not so subtle. But the radiation safety
4 aspects for handling and administering these are
5 while maybe not identical, they are similar enough
6 that the training and education is sufficient.

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

9 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

10 MEMBER LANGHORST: I want to remind the
11 Committee that the question at hand has only to do
12 with the work experience that is required. The fact
13 that we're suggesting not splitting between beta
14 gamma, and alpha doesn't mean that an Authorized
15 User physician would not get trained in both. That
16 is going to be much more prevalent as we get more
17 of these alpha-emitting radiopharmaceuticals in
18 use.

19 So, it is the parenteral administration
20 and that work experience that we're saying let's
21 not add to the confusion of saying okay, you've got
22 three cases of alpha and three cases of beta gamma.
23 If you have three of any combination of those, that
24 is work experience in determining a parenteral
25 administration. And with all the additional

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1 training that these Authorized Users get, that
2 covers the full breadth, as Pat was talking about
3 in regard to medical oncology and chemotherapy.

4 So, Laura, I wanted to assure you they
5 still get training in all of this, and may get work
6 experience, but we're saying don't split it that
7 fine into those two different categories that then
8 I as a radiation safety officer have to tally up
9 who's got what parenteral administrations, and if
10 they're already an Authorized User do they have to
11 go back and get it? And it just -- that's, I think,
12 an unnecessary bookkeeping requirement that
13 splitting them would impose upon us. Thank you.

14 CHAIRMAN MALMUD: Thank you. Laura, has
15 the issue been clarified for you to your
16 satisfaction with regard to your concern?

17 MEMBER WEIL: I certainly am grateful
18 for the clarification of other members of the
19 Committee's comments, but I'm concerned that staff
20 seemed to have a very different perspective about
21 this. And given that there's very little input from
22 Staff in this process, I am -- I don't feel that
23 I'm hearing both sides of the argument.

24 MEMBER GUIBERTEAU: Dr. Malmud, this is
25 Mickey Guiberteau. May I --

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1 CHAIRMAN MALMUD: Yes. Dr. Guiberteau.

2 MEMBER GUIBERTEAU: You know, I feel
3 very comfortable, Laura, with the consensus that
4 appears to be developing in terms of the safe
5 handling and administration across a broad spectrum
6 of alpha emitting radio isotopes that there really
7 is little in the way of safety differential in
8 terms of the patient.

9 One of the things that we're -- from
10 the point of view from which you come in terms of
11 safety for the patient and the consumer, there is
12 also the concern of access to care which we always
13 try to balance with any sort of safety regulation.
14 And the opposite of this would be to divide these
15 into two different categories with different bars,
16 and with different work experience required which
17 most of us feel is unnecessary, which does have the
18 potential for creating a differential in access to
19 care which is also unsafe in many circumstances in
20 terms of denying patients or delaying patients in
21 terms of reaching a therapy that may be better for
22 them.

23 So, there is a balance here. I do
24 understand your concerns, but I think in terms of
25 access to care and in terms of the radiation safety

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1 uniformity pretty much between alpha emitters and
2 gamma emitters as we know them, that this -- the
3 way this has been stated by the Committee makes a
4 lot of sense.

5 CHAIRMAN MALMUD: Thank you for your
6 comment, Dr. Guiberteau. Laura, any response?

7 MEMBER WEIL: I have -- yes, the access
8 issue is something that I have thought about it,
9 and it's -- Mickey, you're right. It's an extremely
10 important aspect to this whole question. I'm
11 willing to stop objecting to this; whether I'll
12 agree to it or not, I really haven't decided.

13 CHAIRMAN MALMUD: All right, thank you.
14 Further discussion of this issue? If not, I'll turn
15 it back to Dr. Zanzonico.

16 MEMBER ZANZONICO: Well, thank you all
17 again for some very thoughtful comments, and
18 special thanks to Laura for her thoughts on this.

19 I really don't have any -- personally
20 any further comments to add other than to reinforce
21 what both Dr. Langhorst and Dr. Guiberteau said;
22 namely, that not including a work experience
23 requirement does not at all mean there will not be
24 additional training. Even when new diagnostic
25 radiopharmaceuticals are introduced or new imaging

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1 modalities are introduced, there's often additional
2 -- extensive additional training for the
3 practitioners. And that will certainly be the case
4 for alpha emitting therapy or any other form of
5 radionuclide therapy.

6 And the other key point to consider is
7 one of access. And I -- as Dr. Guiberteau was
8 speaking, I think of the case of some of the
9 radionuclide-based bone palliation agents which
10 really, I think, are very effective, very
11 convenient for the patient, et cetera, et cetera;
12 yet, there seems to be some disconnect between the
13 physicians who care for these patients, typically
14 medical oncologists and the nuclear medicine
15 physicians so that these very effective, safe,
16 convenient therapies don't seem to be used nearly
17 as extensively as they could be or should be. And,
18 again, that's at least in part to training and
19 experience requirements. There are other issues,
20 economic and otherwise involved, but I think the
21 issue of wide access to effective and safe therapy
22 is one we need to consider, as well.

23 Having said all that, I would like to
24 move -- to make a motion that we can vote on that
25 is in our draft report. And I'll read the motion.

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1 CHAIRMAN MALMUD: Thank you. So, the
2 motion passes with one abstention. Thank you, Dr.
3 Zanzonico.

4 MEMBER ZANZONICO: Okay, thank you.

5 So, lest I skip over another item, and
6 I thank Dr. Langhorst for keeping us on track, the
7 next item would then be Agenda Item 3. What I would
8 like to do is read the motion as it appears in our
9 draft report and then solicit comments. There may
10 or may not be, so let me read the recommendation.

11 The ACMUI has recommended and still
12 recommends that the date of recognition of a
13 certifying board should not impact individuals
14 seeking to be named as an Authorized User,
15 Authorized Radiation Safety Officer, Authorized
16 Medical Physicist, or Authorized Nuclear Pharmacist
17 through the certification pathway. So, the essence
18 of that recommendation is that the date of
19 recognition does not -- is irrelevant, in effect.
20 This is in relation to the Ritenour petition and
21 certain other issues, but that's the crux of the
22 recommendation.

23 I don't know if there's -- if anyone
24 has comments to offer, but I would ask if there are
25 any comments that folks come forward with them.

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1 CHAIRMAN MALMUD: Are there any
2 comments?

3 MS. BHALLA: Yes. Dr. Malmud, this is
4 Neelam Bhalla. May I speak on this?

5 CHAIRMAN MALMUD: Absolutely. Thank you.

6 MS. BHALLA: Yes, the entire Ritenour
7 petition is based on grandfathering an individual.
8 And right now under 35.57 in the regs it starts
9 that any individual who's identified on a license,
10 and that identification goes back to 2005 time
11 frame, that person need not comply with the
12 training and experience requirements of the current
13 regulations. So, therefore, that date is very
14 important because after that date, after the 2005
15 revision the boards had to meet certain
16 requirements to meet with the new training and
17 experience requirements.

18 So, therefore, when the petition came,
19 Ritenour's petition came, the petition was that
20 there were individuals who met the old Subpart J
21 requirements in terms of for the medical physicists
22 and for the RSOs, but they didn't have an
23 opportunity to be named on a specific license for a
24 whole lot of different reasons.

25 So, when NRC reviewed the petition,

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1 agreed with the petitioner that yes, the way the
2 rule got written it did compromise some of those
3 people who were boarded, who met our Subpart J
4 requirements, but just because they were not named
5 on a license as of that date they now had to meet
6 the new requirements.

7 So, therefore, when we have now amended
8 this rule to take care of all those individuals and
9 to recognize their board certifications as of the
10 old Subpart J, we need to leave that date. It's
11 very important. Otherwise, if there is no date,
12 then the people who are meeting the new boards,
13 they're already -- they would be -- they would not
14 need this -- they would not fall into the old
15 Subpart J. So, therefore, the 2005 date is crucial,
16 and we would keep it.

17 MR. LOHR: And I have a clarification
18 question, and I believe this is what's being
19 discussed.

20 CHAIRMAN MALMUD: Identify yourself.

21 MR. LOHR: I'm sorry, this is Ed Lohr. I
22 believe what's being identified is the individuals
23 who are boarded after 2005, but before the NRC has
24 recognized that board. I believe the comment was
25 made that all boards regardless of when should be

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1 recognized. And the Ritenour petition did not
2 address that, as Neelam has been saying. It
3 addressed those prior to 2005 when the NRC was
4 recognizing those boards. But there is a so called
5 gap, if you will, between the time from 2005 until
6 the boards were recognized under the new process.
7 And I believe that's what has been brought up by
8 Dr. Zanzonico, but I didn't want to put words in
9 his mouth. I just want to make sure that's what
10 he's talking about.

11 MEMBER ZANZONICO: This is Pat
12 Zanzonico. That's basically it. There does seem to
13 be a gap here that's problematic, or potentially
14 problematic.

15 CHAIRMAN MALMUD: Dr. Zanzonico, is that
16 what you were addressing?

17 MEMBER ZANZONICO: Yes.

18 CHAIRMAN MALMUD: Thank you.

19 MEMBER ZANZONICO: This is Pat Zanzonico
20 again. I guess my question is, and I apologize for
21 being dense on this point. I still don't quite
22 understand what the problem would be with the ACMUI
23 recommendation as I verbalized it. In other words,
24 making the date of recognition of a board by the
25 NRC irrelevant. I don't -- I still don't quite

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1 understand what regulatory issue that would
2 introduce.

3 CHAIRMAN MALMUD: Neelam, could you
4 address that?

5 MS. BHALLA: Sure. What we are amending
6 is 35.57 in the regs; 35.57 starts with people who
7 are ----- okay. It starts with an individual
8 identified as a Radiation Safety Officer,
9 teletherapy physicist and so on, and then they need
10 not comply with the training requirement. So,
11 there's a very specific date in there. And legally
12 that's the part we are amending. We are amending
13 35.57 and we cannot in there go back to -- we can
14 only go back to 2005, and maybe Susan, our legal
15 person, can explain that better.

16 MS. CHIDAKEL: Let me try to explain
17 what we're tried to do here. Okay? The date 2005 --

18
19 CHAIRMAN MALMUD: Excuse me, this is Dr.
20 Malmud. Would you please identify yourself for the
21 Committee.

22 MS. CHIDAKEL: I'm sorry. This is Susan
23 Chidakel from the Office of General Counsel.

24 CHAIRMAN MALMUD: Thank you.

25 MS. CHIDAKEL: And I don't think that --

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1 I think there's a disconnect in what you're seeing
2 in this rule. I don't think your concern is in the
3 -- what's in the rule is not going to -- your
4 concern doesn't connect with this.

5 What we're trying to, as Neelam said,
6 okay, we had a new rule in 2005 in which Subpart J
7 expired. This impacted people who had been
8 certified by the boards listed under Subpart J.

9 What we're trying to do is say all
10 those people who were recognized by boards before
11 the new rule came into effect, whether or not
12 they're listed in a license, they're now -- their
13 certification is good. They're now -- you know,
14 they don't need any more education, or any more
15 recertification, or anything of that sort.

16 The reason the date is in there is
17 because in 2005, those boards were no longer
18 recognized, so we want to make clear that after
19 2005, you know, these new individuals coming in are
20 going to have to have certification by the boards
21 that are now being recognized under the new rule.
22 Am I making sense? Am I making this clear to you?
23 So, it's not impacting -- I guess I don't see the
24 problem. I read your recommendation several dates
25 that the date of recognition should not impact

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1 individuals seeking to be named. I don't see where
2 the date of recognition of a board has anything to
3 do with what we're doing here in this new rule. We
4 don't say anything about the date of recognition of
5 a board.

6 What we're saying is, we're saying any
7 boards that were in existence that have certified
8 people as of the date that Subpart J expired, these
9 people are now recognized, you know, the same as
10 anybody else whether or not they're on a license.
11 So, I don't quite understand the gist of your
12 concern, and I'm wondering if I have alleviated
13 your concern in any way, or made this more clear.

14 CHAIRMAN MALMUD: I think you have
15 clarified it. What do other members of the
16 Committee feel?

17 MEMBER ZANZONICO: This is Pat
18 Zanzonico. I think you've clarified it, as well. My
19 concern -- and, again, I think you clarified it,
20 was that individuals who might have been board
21 certified -- whose board may -- who may be
22 certified by a board which was recognized after
23 this date somehow fell through the cracks. But
24 you're assuring me that's not the case.

25 MS. CHIDAKEL: No. The whole idea is to

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1 -- using 2005 is the point where the new rule came
2 into effect and we had boards now that had to come
3 in for certification. Donna-Beth, did you want to
4 add something?

5 DR. HOWE: Yes, this is Dr. Howe. When
6 we changed the rule in 2005, all the boards had to
7 come in to be recognized. And there were new
8 criteria for them to be recognized. Not all of the
9 boards met the new criteria on the date that the
10 rule came into effect and many boards -- I won't
11 say many, but a number of boards had to change
12 their program so they could comply with the new
13 criteria for recognizing the board. And that may
14 have taken a year, two years, or longer, so there
15 are boards that were continuing to issue
16 certificates but they did not meet the NRC
17 requirements 2005 until the date that they're
18 recognized on our website, which was -- an
19 individual date was negotiated for each board.

20 So, in some cases for the nuclear
21 pharmacy board, it's totally moot. We recognize the
22 nuclear pharmacy board from almost day one. There
23 was no gap. For other boards like nuclear medicine
24 they had diplomates that didn't receive training
25 under Authorized Users, and our regulation said we

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1 could only recognize those that had training under
2 Authorized Users, so there became a distinction
3 between different board certifications whether they
4 were in the U.S., or outside of the U.S. So, we
5 have specific certificates that are recognized
6 because the process that goes with those
7 certificates are recognized by NRC.

8 MS. CHIDAKEL: But the point is that
9 even if the -- you know, no matter what happened
10 with the boards and whether they were recognized in
11 2005 or not, if individuals were certified by those
12 boards before 2005, they can continue to practice.
13 They don't need additional education. This is what
14 we're trying to do. We're trying to -- that's what
15 we're trying to fix.

16 This issue that Donna-Beth is raising,
17 that was a board problem, but if an individual had
18 been recognized when the new rule came into effect,
19 they're good.

20 MEMBER ZANZONICO: This is Pat
21 Zanzonico. That still raises an issue because after
22 the date of expiration of Subpart J, if an
23 individual was certified by a board after that date
24 but that board was not recognized until
25 subsequently because its training and experience

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1 requirements were deemed inadequate by the NRC,
2 what happens to that individual who was board
3 certified after the expiration date of Subpart J,
4 but before the recognition of that board by the
5 NRC?

6 DR. HOWE: There's not a clear -- this
7 is Dr. Howe. There's not a clear answer to that,
8 because in some cases the boards recognized that
9 they had maybe one or two years in which their
10 board certificates were not recognized, and they
11 went back. But they believed that their candidates
12 did meet the criteria. It's just their processes
13 didn't state exactly what we needed, so they went
14 back and picked up the few individuals that weren't
15 Authorized Users. Mainly, this is for the medical
16 board, and picked up the Authorized Users that
17 weren't listed yet, and had a process where they
18 could reissue a certificate that had the boards we
19 were looking for in them so that we could recognize
20 them back to an earlier date. And that's specified
21 in our website.

22 There are a number of other boards that
23 did not do that, and did not want to go back, so
24 they are recognized from a specific date forward. I
25 think the Health Physics Board is an example where

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1 they're recognized at a certain date that's not
2 2005 because they did not want to go back and
3 verify the training and experience met our criteria
4 even though their criteria was much broader than
5 ours. Individual members could meet our criteria,
6 but the board itself didn't until a certain date.

7 MR. LOHR: This is Ed Lohr again. I
8 believe to answer the question a little more
9 bluntly is those people in the gap are still
10 required to come through alternate pathways, and we
11 do not at the NRC recognize that board
12 certification.

13 MEMBER ZANZONICO: I guess -- I mean,
14 that really puts a point on it, and I think really
15 is the essence or the motivation for this
16 rationale. I mean, frankly, that strikes me as not
17 right. You know, an individual met training and
18 experience requirements for professional board
19 certification, and a board that was recognized by
20 the NRC. And they're effectively being told that,
21 you know, because of an accident in time of when
22 they were certified, that their certification is
23 not acceptable.

24 Practices change, training and
25 experience requirements change, and so forth. It

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1 seems unfair to those individuals to penalize them
2 on that basis when they had met the prevailing
3 training and experience requirements at the time
4 they were certified.

5 DR. HOWE: Dr. Zanzonico, this is Dr.
6 Howe. For the most part what you're saying is true,
7 but you cannot make that assumption across the
8 board, because we did have a number of boards that
9 were nowhere near meeting the recognition criteria.
10 And they had to totally restructure. They weren't
11 necessarily giving examinations to test people,
12 they didn't have criteria for people to be board
13 certified that came anywhere close to what was
14 being recognized afterwards, so there is no clear
15 cut date that you can say everybody is covered,
16 because we did have a few boards that just were
17 totally inadequate in criteria.

18 MS. BHALLA: Dr. Malmud, this is Neelam
19 Bhalla. May I speak?

20 CHAIRMAN MALMUD: Please do.

21 MS. BHALLA: Yes. So, for the purposes
22 of this rulemaking, the NRC Staff when we resolved
23 this petition, Ritenour's petition, we have -- we
24 are obligated to -- we are under, I suppose, as a
25 condition of that petition resolution, that we need

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1 to amend our regulation in 35.57. And that relates
2 to strictly people who got boarded under the old
3 Subpart J; so, therefore, so far as the Ritenour
4 petition goes and amending 35.57, according to
5 that, that's what we have done. And anything beyond
6 about this added issue about -- this is beyond the
7 scope of the Ritenour petition.

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

10 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

11 MEMBER LANGHORST: I think the Committee
12 voiced its opinion in September and probably a
13 couple of different times that we don't think that
14 people who are board certified just by the fact of
15 their having been certified a year after this
16 October 2005, and their board wasn't through, it
17 just does not seem fair that a person who was board
18 certified right before that date can meet this
19 criteria, but the person just a year after
20 potentially could not meet that criteria that is in
21 35.57.

22 As the Part 35 rules have changed,
23 Section 35.57 has gotten more and more complex. And
24 let me tell you, as an RSO it confuses me to no
25 end, so I think we all are in agreement that we

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1 would like to kind of start with a clean slate so
2 that board certified individuals have an
3 opportunity to practice their profession, and I --
4 from a personal point of view, I hope that NRC
5 takes this opportunity to try to simplify 35.57 as
6 much as possible, because it's just near impossible
7 to understand. So, thank you very much.

8 CHAIRMAN MALMUD: Thank you. This issue
9 has come up repetitively, and I think we all
10 understand why the interpretation was given to it
11 by the NRC, but I think the vast majority of us
12 don't agree with it. Is that a fair statement?

13 (Chorus of yeses.)

14 CHAIRMAN MALMUD: So, we are asking the
15 NRC to recognize that we do not feel that the
16 solution that was arrived at, though logical, is
17 practical, and we are concerned that it will
18 interfere with the practice of the specialties
19 involved. And, therefore, we would encourage the
20 NRC to attempt to resolve this for us in some
21 regulatory fashion that would not exclude people
22 from practicing who we feel by virtue of their
23 training are qualified despite the fact that their
24 boards may not have responded to the NRC's repeated
25 requests to meet those standards at that time; that

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1 this is a deficiency in documentation rather than a
2 deficiency that's been demonstrated to be in
3 practice. It's a deficiency in documentation, and
4 perhaps some exception can be worked out so this
5 can be resolved, because we're concerned about the
6 availability of these people to practice their
7 specialties on behalf of patient care.

8 MEMBER ZANZONICO: Dr. Malmud, this is
9 Pat Zanzonico. I would just like to append your
10 statement with the fact that we concede this is a
11 separate but perhaps related issue from the
12 Ritenour petition and is outside the scope of the
13 NRC's response to that petition, but we think it
14 warrants some remediation, nonetheless.

15 CHAIRMAN MALMUD: Thank you, and that's
16 what we're requesting of the NRC Staff and its
17 legal consultants. We're seeking a practical
18 solution to a practical problem that will affect
19 some practitioners in a way which we feel is not in
20 the best interest of the end product which is
21 patient care. May we move on, because we're not
22 going to resolve that particular element of this
23 discussion this conference call.

24 MEMBER ZANZONICO: Understood. I guess
25 my question is, and this is really for members of

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1 the ACMUI, should we -- do we feel we want to vote
2 and include -- vote on and include this
3 recommendation in our report or not in light of the
4 NRC staff's explanations and clarifications?

5 CHAIRMAN MALMUD: Well, I think that the
6 --from the voices that I heard on the phone, the
7 vast majority agrees with your position, Dr.
8 Zanzonico.

9 MEMBER ZANZONICO: Okay.

10 CHAIRMAN MALMUD: And I think that the -
11 - we recognize the nature of why the decision --
12 recommendation was made by the NRC. They are
13 driven by the law, and the law must be adhered to.
14 At the same time, it's an impractical solution
15 given the fact that there's a cutoff date which had
16 to do with the law, but would interfere with
17 individuals who are competent to do what they had
18 been doing, but whose boards for a variety of
19 reasons which are difficult to understand, did not
20 meet the NRC request for documentation at that
21 time. So, all we can say is that we favor a
22 generous solution to the existing problem. It's not
23 a larger problem as 11 million undocumented aliens
24 and, therefore, we feel that solution might be able
25 to be worked out given some effort, additional

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1 effort by the NRC staff and legal department in
2 working with perhaps even the Commissioners
3 themselves to resolve a very practical issue which
4 doesn't affect an enormous number of people, but
5 could cause some individuals some embarrassment.
6 And, therefore, you can put your motion forward,
7 Dr. Zanzonico.

8 MEMBER ZANZONICO: Okay. Then I'll make
9 the motion that we adopt the following
10 recommendation; that is, that the date of
11 recognition of a recognized -- the date of
12 recognition of a certifying board should not impact
13 individuals being named as authorized
14 professionals, AUs, Authorized RSOs, et cetera, so
15 that is the motion.

16 CHAIRMAN MALMUD: That is the motion. Is
17 there a second to that motion? I don't hear a
18 second.

19 VICE CHAIR THOMADSEN: This is Bruce
20 Thomadsen.

21 CHAIRMAN MALMUD: Dr. Thomadsen. You
22 seconded it?

23 VICE CHAIR THOMADSEN: Yes.

24 CHAIRMAN MALMUD: Thank you. Is there
25 further discussion?

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1 (No response.)

2 CHAIRMAN MALMUD: We recognize that we
3 are making a recommendation as a consulting body,
4 and that it may -- a portion of it may be not
5 approved, but we want the spirit of the
6 recommendation to be clearly transmitted to the
7 interested parties in the best interest of
8 maintaining the ability of individuals to practice
9 on behalf of the public. So, all in favor of the
10 motion?

11 (Chorus of ayes.)

12 CHAIRMAN MALMUD: Any opposed? I hear no
13 opposition. Any abstentions?

14 (No response.)

15 CHAIRMAN MALMUD: So, the motion is
16 passed unanimously which should assist in
17 addressing the importance of the issue including
18 that element of it to the bodies that we consult
19 for within the NRC.

20 Dr. Zanzonico, any other items?

21 MEMBER ZANZONICO: Yes, there are. So,
22 we want to move on to Item 4 in our report, and
23 this has to do with the measuring moly
24 breakthrough, and reporting of failed breakthrough
25 tests. And to expedite matters on this point, there

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1 -- I think we are all in agreement, we on the ACMUI
2 are all in agreement with the provisions of the
3 proposed rule requiring testing of moly
4 breakthrough on every elution of a moly-tech
5 generator rather than after only the first elution.

6 There are two contentious issues,
7 though, which have arisen in the course of our last
8 teleconference and subsequent emails. The first of
9 these is related to the reporting of out-of-
10 tolerance breakthrough results.

11 The proposed NRC rule, as I understand
12 it, is requiring a reporting to the -- by the user,
13 by the licensee requiring reporting of out-of-
14 tolerance elution results, breakthrough results to
15 the NRC, and to the manufacturer.

16 The two options are reporting the
17 results only to the manufacturer and leaving it to
18 the manufacturer to report these results to the
19 NRC. And the second option would be to recommend
20 the proposed NRC rule requiring dual reporting.
21 That's the first issue.

22 The second issue is related to
23 generators not included in the covered proposed
24 rule, and there was concern among the ACMUI members
25 that -- about generators that might be introduced

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1 in the near future like germanium/gallium
2 generators and what to do with those in terms of
3 breakthrough testing. And one possibility would be
4 to the -- for the NRC to generalize its rule to
5 address future generator systems, and the
6 alternative would be that the NRC by regulation
7 adopt the FDA label instructions, the package
8 insert for generator QC procedures. And the
9 rationale for that latter approach would be that it
10 would not require revision of NRC rules as each new
11 generator system is introduced.

12 So, those are the two issues. And I
13 guess we should take them one at a time; the first
14 one being reporting of out-of-tolerance results. If
15 there's any discussion or comment on reporting
16 requirements to both the NRC and the manufacturer
17 versus the manufacturer only. So, at this point I
18 would solicit comments from the Committee on that
19 point.

20 MEMBER VAN DECKER: Dr. Malmud.

21 CHAIRMAN MALMUD: Yes, thank you.

22 MEMBER VAN DECKER: This is Bill Van
23 Decker. Can I speak to that first?

24 CHAIRMAN MALMUD: Yes, Dr. Van Decker.

25 MEMBER VAN DECKER: I think that the

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1 Subcommittee did a fairly thoughtful go-around on
2 your first draft here. I would say I would tend to
3 personally agree with that draft. I don't think
4 that anyone disagrees with the fact that generators
5 are important items in the process of delivering
6 dose to a patient, and we have to have a great QMP
7 program for each generator, and a good QC program,
8 but we also have to recognize that breakthrough
9 unto itself is not a medical event, although it
10 certainly can lead to the opportunity to have one,
11 and is something that's going to take some
12 investigation and some look into things before it
13 really gets settled out.

14 In a busy clinical world where people
15 are trying to give access to care at the same time,
16 you know, a call to a manufacturer who's helping in
17 the piece of the troubleshooting, and then he's
18 kind of mandated to take that to the NRC in a more
19 streamlined manner than licensee having to make
20 multiple reports in multiple places with multiple
21 time lines, just adds a lot of complexity to the
22 overall situation.

23 I don't think we all disagree with the
24 concept of everyone in the current era with current
25 histories and everything else wants to be as sure

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1 as possible. And I think the practicing community
2 wants that to be true, as well, but we think that
3 reporting to -- or I think a lot of people feel
4 that reporting to a manufacturer as an initial
5 step, and at least at that point having made sure
6 that you've done your QC, your QMP correctly, and
7 do some troubleshooting from there is a very
8 reasonable process indicator for where you need to
9 be, and not a medical event unto itself. And that
10 would kind of be my concept of this, and I'm happy
11 to hear from others.

12 CHAIRMAN MALMUD: Dr. Van Decker is
13 seeking other opinions.

14 MEMBER PALESTRO: Dr. Malmud.

15 CHAIRMAN MALMUD: Yes, sir.

16 MEMBER PALESTRO: Chris Palestro. I
17 disagree a bit with Dr. Van Decker. I don't have
18 any experience with rubidium generator but
19 certainly have had 30 years of experience with the
20 molybdenum-technetium generator because that's all
21 we've ever used. We don't use the unit doses. And I
22 have to -- cannot recall a single incident of
23 molybdenum breakthrough in any of the generators
24 that we use at the various locations that I've been
25 over the course of my career. So, while the

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1 reporting may be a bit cumbersome and time
2 consuming, it's something that I think happens so
3 infrequently that that shouldn't be governing
4 whether or not we want dual reporting.

5 My concern with the manufacturer, quite
6 frankly, is I'm not a big fan of manufacturers.
7 They have other items on their agenda, and I think
8 that dual reporting is better than going through
9 the manufacturer.

10 MEMBER SULEIMAN: Dr. Malmud, Orhan
11 Suleiman.

12 CHAIRMAN MALMUD: Yes, I was just about
13 to thank him for his opinion. And, Dr. Suleiman,
14 your opinion is welcome.

15 MEMBER SULEIMAN: Okay. This is
16 basically from real life experience. Breakthrough
17 does not occur very often, but it does occur, and
18 there was a case a few years ago where a user was
19 getting breakthrough and reporting it to the
20 manufacturer. And this kept on going on, and the
21 generator -- he was getting a generator replaced.
22 Eventually he got fed up because he -- this was a
23 recurring problem and it was something he hadn't
24 experienced before. So, he reported it to the NRC,
25 who shared that information with us.

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1 It took a while for the investigation
2 to follow but there was a manufacturing issue
3 underlying the problem. It doesn't happen often,
4 but in terms of trends if you get maybe a bad batch
5 of molybdenum or a bad batch of the column, the
6 chemical that makes the column, you may start to
7 see breakthrough across multiple sites, and
8 everyone will say well, it's just one thing, I'm
9 not going to bother. But if there's -- it's sort of
10 an early warning thing. And I don't think anybody
11 I've spoken to thinks that it would be burdensome
12 to just -- I wouldn't expect that the NRC reporting
13 requirement would be massive in terms of paperwork,
14 but that's sort of saying, you know, we picked up
15 the moly. And it's also a system of checks and
16 balances.

17 When you rely solely on the
18 manufacturer and a lot of manufacturers are good,
19 and professional, and we learn a lot from their
20 expertise, but there's also always the temptation
21 of conflict of interest. So, they may want to solve
22 the problem before they -- you know, let's take
23 care of this. This is not a really serious problem.
24 And by the time they come to the conclusion that
25 maybe it is a more serious problem, it may have

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1 proliferated. So, I think it's a very prudent and
2 simple requirement.

3 CHAIRMAN MALMUD: Thank you, Dr.
4 Suleiman. We've heard from two members of the
5 Committee both of whom are supportive of the dual
6 reporting line, both the manufacturer and the NRC.
7 Are there any voices in support of that, as well,
8 or who oppose that?

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

11 CHAIRMAN MALMUD: Yes, Steve.

12 MEMBER MATTMULLER: And I do have a few
13 comments in regards to this. I believe the
14 justification for the proposed reporting
15 requirements have misidentified past incidents as
16 radiation safety incidents but, in fact, they are a
17 product quality issue.

18 The breakthrough test in question is a
19 radiopharmaceutical product quality control test.
20 The testing procedure is clear. The licensee is to
21 perform the measurement for breakthrough before the
22 product is used. If the product passes the
23 measurement, then it may be used for patients. If
24 the product fails the measurement then it may not
25 be used for patients.

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1 The discussion within the proposed rule
2 misses this fact, I think, from past incidents;
3 that is, when pharmacists found breakthrough limits
4 that were exceeded in their technetium-99m
5 elutions, they discarded the elution, patients were
6 not injected. If a product fails this measurement
7 it's a product quality issue that is best solved by
8 the licensee contacting the manufacturer.

9 If a licensee has a generator that
10 fails breakthrough testing they are, in essence,
11 out of business. If they want to return to
12 business, they have to call the manufacturer
13 because only the manufacturer can supply a
14 replacement generator for the defective generator.
15 And believe me, this is a strong incentive for a
16 licensee to contact a manufacturer.

17 For well over a decade it's been
18 standard practice for any licensee who uses a
19 generator to also use the computer system such as
20 biodose or NMIS, or their own in-house system such
21 as ones developed by Triad and Cardinal.

22 An important component of these
23 computer systems is the calculations that are
24 automatically performed for moly-99 breakthrough
25 testing. As one assays the technetium-99m and the

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1 moly content of an elution, this information is
2 entered into the program and it automatically
3 calculates the ratio of technetium to moly.

4 If it passes, it's good to go. If it
5 doesn't pass, it can't be used for making -- for
6 kits or for being used to dispense for doses. In
7 fact, some pharmacies now are even going one step
8 further and they're printing the moly-99 content on
9 the individual technetium-99m unit dose labels.

10 The same steps apply to the strontium-
11 82, rubidium-82 generator except that instead of an
12 in-house computer system the assay results of the
13 elution are now entered into an online system
14 monitored by Bracco. If an elution with substandard
15 product quality is disposed of and not administered
16 to patients, how would the NRC ever see a report of
17 a radiation safety issue in a patient?

18 In other words, if a licensee is
19 following the regulations and performing a
20 breakthrough test, the NRC will only see reports
21 regarding product qualities or issue regarding
22 product quality.

23 So, I would say the NRC responsibility
24 is patient safety. The best way to insure patient
25 safety is that a safe product is being used. The

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1 best response from the NRC should be to do the
2 breakthrough testing according to FDA product
3 labeling.

4 I'd also like to make a few additional
5 comments on the rationale listed in the proposed
6 regulations as justifications for the new reporting
7 requirements. One of the first --

8 CHAIRMAN MALMUD: Steve?

9 MEMBER MATTMULLER: Yes?

10 CHAIRMAN MALMUD: I just want to
11 interrupt you for a moment, and that is, therefore,
12 you are arguing against the dual reporting line.

13 MEMBER MATTMULLER: Yes, I am.

14 CHAIRMAN MALMUD: Thank you. I just
15 wanted to clarify that. Now, please go ahead.

16 MEMBER MATTMULLER: Not a problem. The
17 first justification was that the FDA may not
18 investigate each reported incident and may take a
19 considerable amount of time in investigating the
20 cause of reported failures. This is probably an
21 accurate description of past FDA actions, but
22 without knowing the specifics of each event, this
23 is probably an entire appropriate action by the
24 FDA.

25 According to FDA current good

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1 manufacturing practices, if a manufacturer gets a
2 product complaint, there are several standard
3 operating procedures in place that they must
4 follow. One of these standard operating procedures
5 is that the manufacturer will start an
6 investigation as to the cause of the problem, and
7 the result of the investigation and any proposed
8 modifications to the manufacturing process, and any
9 validation studies of these modifications will all
10 be available for FDA review.

11 Even though the FDA may not have its
12 inspectors in the manufacturer's facility at the
13 time, in a very big way an inspection is being
14 conducted in a manner approved by the FDA. Think of
15 these standard operating procedures as
16 representative of its in-house FDA office within
17 the manufacturing site in that these SOPs, or
18 standard operating procedures are all FDA approved
19 and they direct the actions of the manufacturer in
20 these and all other situations.

21 I'll skip to the third and come back to
22 the second. The third statement was, additionally,
23 some incidents of failed generators may not be
24 reported to the FDA because certain manufacturers
25 are not in the United States. And the generators

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1 are distributed by vendors who are not required to
2 report to the FDA.

3 Whether or not a company's headquarters
4 or its manufacturing site is inside or outside of
5 the United States is misleading. If a product is
6 used in the United States, it will have FDA
7 approval. Its application for this drug, its
8 standard operating procedures, its manufacturing
9 site will all be reviewed, inspected, and approved
10 by the FDA before the product comes to market.

11 If a licensee's generator is not
12 performing well and that licensee can't use it for
13 their patients, they will contact the manufacturer,
14 as only the manufacturer can send them a
15 replacement generator.

16 There was also a statement about how
17 the generators are distributed by vendors who are
18 not required to report to the FDA. I'm not clear to
19 the intent of this because to my knowledge the vast
20 majority of generators are sold direct to the
21 licensee by the manufacturer; 95 percent of all
22 technetium generators are sold direct to commercial
23 nuclear pharmacies. The other 5 percent are sold
24 direct to large medical institutions such as
25 Massachusetts General or Sloan-Kettering. All the

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1 rubidium-82 generators are sold direct by Bracco.

2 If there is a unique example of a
3 vendor distributing a generator that would
4 represent a very small percentage of all
5 generators, it would be doubtful this small number
6 could justify a regulatory action. Plus, in a sense
7 it doesn't matter. A failed generator is a failed
8 generator. Even if a vendor is involved, the
9 licensee is out of business. If a vendor is
10 contacted by the licensee that they have a failed
11 generator, the vendor has to contact the
12 manufacturer to arrange for a replacement generator
13 for the licensee.

14 In regards to the second statement, the
15 NRC believes that requiring each incident of a
16 failed generator to be reported would provide the
17 NRC the opportunity to evaluate and take prompt
18 action, as needed.

19 Again, these are not radiation safety
20 issues; these are drug quality issues, clearly in
21 the realm and expertise of the FDA. The generator's
22 manufacturer radioactive materials license is for
23 the safe use of radioactive material within their
24 manufacturing facility. This license is concerned
25 with items such as radiation exposure to the

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1 employees, proper security of the radioactive
2 material, and proper disposal of radioactive waste.
3 These are all areas of the NRC's expertise and
4 regulatory charge.

5 A manufacturer's radioactive material
6 license, though, from the NRC should not be used as
7 a pathway to investigate a manufacturer's
8 manufacturing procedures. These procedures are
9 clearly the expertise of the FDA.

10 To allow the NRC a pathway to
11 investigate manufacturer's procedures would be akin
12 to allowing the FDA to investigate operating
13 procedures at a nuclear power plant. It would be
14 inappropriate.

15 But even if these reports are allowed,
16 any subsequent investigation by the NRC will have a
17 very unequal effect on the various generator
18 manufacturers. One has to remember that the NRC's
19 regulations are enforced by 37 Agreement States in
20 the U.S. And just as the NRC really does not have
21 the appropriate staff, such as a chemical engineer
22 or a radiochemist with FDA manufacturing
23 experience, neither do the respective Agreement
24 State Radiation Protection Programs.

25 As a reminder, the Covidien

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1 manufacturing sites in St. Louis, Missouri, the
2 Lantheus manufacturing sites in Boston,
3 Massachusetts, and one of the manufacturing sites
4 for the Bracco rubidium generator is in Ottawa,
5 Canada.

6 There are a couple of scenarios to
7 consider for this. The first one would be
8 breakthrough is found in a licensee in Missouri
9 from a Covidien generator that was manufactured in
10 Missouri. The licensee sends a report to the NRC.
11 If the NRC decides an inspection is needed, they
12 can inspect right away.

13 In scenario two, breakthrough to be
14 found by a licensee in Ohio from a Lantheus
15 generator that was manufactured in Massachusetts.
16 The licensee sends a report to the Ohio Bureau of
17 Radiation Protection. The Ohio Bureau sends a
18 report to the NRC. If the NRC decides an inspection
19 is needed, they have to suggest this to the
20 Massachusetts Radiation Control Program. Does the
21 Massachusetts program have to act? And, if so, to
22 what extent? So, as demonstrated in the recent
23 rubidium-82 generator incident, the NRC only had an
24 advisory role as the manufacturing site was in New
25 Jersey.

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1 And the third scenario, breakthrough is
2 found by a licensee from a Bracco generator that
3 was manufactured in Canada. The licensee sends the
4 report to the NRC. If the NRC decides an inspection
5 is needed, they can't because they have no
6 authority in Canada.

7 Actually, the third justification
8 listed regarding manufacturers outside of the U.S.
9 is not a problem for the FDA, but it is a problem
10 for the NRC. And can an agency legally promulgate a
11 regulation when they know that any subsequent
12 regulatory action will be unequally applied? So,
13 clearly the NRC should leave the manufacturer of
14 radiopharmaceuticals to the FDA.

15 In all three examples above, the FDA
16 can inspect the manufacturing facilities regardless
17 of state or international borders. There should not
18 be any additional reporting requirement.

19 This is the same recommendation from
20 the participants in the two workshops held by the
21 NRC on this proposed regulation. The NRC should
22 continue to emphasize adherence and expect the
23 35.204 but there should be no additional reporting
24 requirements. Thank you.

25 CHAIRMAN MALMUD: Thank you, Steve. Any

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1 further comments? We've now heard both sides, those
2 in favor of dual reporting, and those in favor of
3 reporting only to the FDA. Any further discussion?

4 (No response.)

5 CHAIRMAN MALMUD: Pat.

6 MEMBER ZANZONICO: Yes, shall we make a
7 motion?

8 CHAIRMAN MALMUD: Please do.

9 MEMBER ZANZONICO: Then the motion I
10 would propose, even though it's not explicitly
11 included in our draft report but I think it's worth
12 making is -- the motion would be that the ACMUI
13 endorses the provision in the proposed rule for
14 reporting of out-of-tolerance moly breakthrough
15 results to the NRC. So, that would be an up or down
16 vote, that the ACMUI either endorses or does not
17 endorse that provision.

18 MEMBER MATTMULLER: Dr. Malmud, this is
19 Steve Mattmuller again. Pat, could you read that a
20 little bit slow --

21 MEMBER ZANZONICO: Yes.

22 MEMBER MATTMULLER: Technetium
23 generators but all generators.

24 MEMBER ZANZONICO: Certainly, we can
25 vote on that point, and I understand the rationale.

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1 So, the -- we're voting on a motion to recommend
2 reporting of out-of-tolerance breakthrough results,
3 generator breakthrough results to the NRC. So,
4 again, it's and up or down vote, we're recommending
5 reporting of such results to the NRC, or recommend
6 -- or not reporting such results to the NRC.

7 CHAIRMAN MALMUD: But, Dr. Zanzonico,
8 your motion is that it be reported.

9 MEMBER ZANZONICO: Correct.

10 CHAIRMAN MALMUD: That is an up or down
11 vote.

12 MEMBER ZANZONICO: Correct. Correct,
13 that's the motion.

14 CHAIRMAN MALMUD: Is there a second to
15 that motion?

16 MEMBER WEIL: This is Laura Weil, I'll
17 second.

18 CHAIRMAN MALMUD: Laura Weil seconds the
19 motion. So, the motion has been moved and seconded
20 that the breakthrough be reported to the NRC.

21 MEMBER LANGHORST: Dr. Malmud, this is
22 Sue Langhorst.

23 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

24 MEMBER LANGHORST: I'd like that motion
25 clarified that notification to NRC, you're talking

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1 about the licensee who is using the generator.

2 MEMBER ZANZONICO: Correct. Correct.

3 This is a reporting requirement for the licensee.

4 MEMBER LANGHORST: Thank you.

5 CHAIRMAN MALMUD: Thank you for that
6 clarification, Dr. Langhorst and Dr. Zanzonico. So,
7 the motion is that the licensee report this to the
8 NRC. All in favor of the motion?

9 (Chorus of ayes.)

10 CHAIRMAN MALMUD: Any opposed to the
11 motion?

12 (Chorus of ayes.)

13 CHAIRMAN MALMUD: We'll have to take a
14 vote then, and we'll have to do this by each
15 individual identifying himself or herself. So,
16 those in favor of the motion are, number one, Dr.
17 Zanzonico.

18 MEMBER ZANZONICO: In favor, yes.

19 CHAIRMAN MALMUD: Number two, who
20 seconded the motion?

21 MEMBER WEIL: Laura Weil.

22 CHAIRMAN MALMUD: Laura Weil, number
23 two. Number three in favor?

24 MEMBER PALESTRO: Chris Palestro.

25 CHAIRMAN MALMUD: Dr. Palestro. Number

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1 four?

2 MEMBER SULEIMAN: Orhan Suleiman.

3 CHAIRMAN MALMUD: Dr. Suleiman. Number

4 five?

5 VICE CHAIR THOMADSEN: Bruce Thomadsen.

6 CHAIRMAN MALMUD: Dr. Thomadsen. Six? Is

7 there a sixth?

8 (No response.)

9 CHAIRMAN MALMUD: I do not hear a sixth.

10 Those opposed to the motion? Number one? Steve?

11 MEMBER MATTMULLER: Steve, yes.

12 CHAIRMAN MALMUD: Number two?

13 MEMBER LANGHORST: This is Sue

14 Langhorst. I'm opposed.

15 CHAIRMAN MALMUD: Dr. Langhorst. Number

16 three?

17 MEMBER BAILEY: Darice Bailey.

18 CHAIRMAN MALMUD: Thank you. Number

19 four?

20 MEMBER VAN DECKER: Van Decker.

21 CHAIRMAN MALMUD: Dr. Van Decker. Number

22 five?

23 MEMBER WELSH: Jim Welsh.

24 CHAIRMAN MALMUD: Dr. Welsh. Six?

25 MEMBER SUH: John Suh.

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1 CHAIRMAN MALMUD: Dr. Suh. Seven?

2 MEMBER GUIBERTEAU: Mickey Guiberteau.

3 CHAIRMAN MALMUD: Dr. Guiberteau. Eight?

4 So, the motion fails by a vote of 7-5. The Chair
5 has not voted. Thank you.

6 Now, Dr. Zanzonico, you have another
7 motion, do you not?

8 MEMBER ZANZONICO: Yes, well another
9 issue I think that warrants discussion on the
10 generator issue. And it's not unrelated. And this
11 has to do with future generators. And the issue is
12 whether the ACMUI should recommend that the NRC
13 adopt FDA label instructions for QC procedures for
14 radioisotope generators.

15 The first -- one alternative would be
16 no, that the NRC promulgates its own required QC
17 procedures. And, obviously, the other alternative
18 would be that yes, the NRC adopt the FDA label
19 instructions. And, again, the advantage of the
20 latter to my way of viewing is that as new
21 generators become marketed products there will be
22 built-in QC procedures as part of the package
23 insert. So, it wouldn't require a revised
24 rulemaking by the NRC to incorporate these new
25 generators into its regulatory oversight, the scope

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1 of its regulatory oversight. So, that is an issue
2 open for discussion, and I would invite comments
3 from the Committee.

4 CHAIRMAN MALMUD: Thank you, Dr.
5 Zanzonico. Are there comments?

6 MEMBER BAILEY: Yes, this is Darice
7 Bailey.

8 CHAIRMAN MALMUD: Yes.

9 MEMBER BAILEY: I would like to clarify
10 from a regulatory standpoint whether you're saying
11 that NRC should, or the Agreement States, whatever,
12 should adopt FDA's label or if through rule or
13 license conditions require the licensee -- that the
14 licensee follows the package insert, which is
15 different things.

16 MEMBER ZANZONICO: Yes. This is Pat
17 Zanzonico. I would -- it's a subtle but I
18 understand important distinction, and to my way of
19 thinking, I would personally recommend the latter.

20 MEMBER BAILEY: I would, too.

21 MEMBER ZANZONICO: Yes.

22 CHAIRMAN MALMUD: Thank you for
23 clarifying that. Other comments?

24 MEMBER SULEIMAN: Dr. Malmud, this is
25 Orhan Suleiman.

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1 CHAIRMAN MALMUD: Dr. Suleiman.

2 MEMBER SULEIMAN: I want to clarify that
3 it's not accepting an FDA approved label. This is
4 the manufacturer's operating instructions. This
5 whole thing is put together by the manufacturer,
6 though we eventually approve it, so it's not like
7 our version versus theirs. And a point of
8 distinction, though I don't know different people
9 interpret it differently, I think what we were
10 focusing on was the breakthrough limit as specified
11 in the label. Obviously, how they do breakthrough
12 is important and should be following the
13 manufacturer's instructions.

14 A third point is that recently, for
15 example, the strontium-rubidium generator, the
16 manufacturer decided to lower the breakthrough
17 limit, so the NRC through rulemaking has etched in
18 the regulations a limit that the company has now
19 changed. So, this would give the NRC a little bit
20 more flexibility in that they could say, you know,
21 the limit is what the label specifies, so if you
22 get a new generator where maybe the impurities are
23 even less, they want to change the limit, you get a
24 different type of generator, you have a completely
25 different, you know, specified amount of

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1 radionuclide per breakthrough. That would all be
2 taken care of very easily, and that way it would
3 also allow for making changes in manufacturing.

4 CHAIRMAN MALMUD: Thank you, Dr.
5 Suleiman. So, you're speaking in favor of the NRC
6 asking that the manufacturer's label, which is
7 eventually approved by the FDA, be the guideline.

8 MEMBER SULEIMAN: Be the regulation.

9 CHAIRMAN MALMUD: Be the regulation. Did
10 I interpret that correctly?

11 MEMBER SULEIMAN: And, in fact, they've
12 always done that with the label, but then
13 manufacturers may change the requirement, and the
14 NRC is stuck holding a regulation that's outdated
15 that then has to go through rulemaking to change.

16 CHAIRMAN MALMUD: When the manufacturer
17 changes the label doesn't that require FDA
18 approval?

19 MEMBER SULEIMAN: Oh, yes. Oh, yes. In
20 other words, for a manufacturer to change the label
21 they file what is known as a supplement.

22 CHAIRMAN MALMUD: Yes.

23 MEMBER SULEIMAN: And they say we want
24 to make these changes. You know, we've learned some
25 new things, we want to -- for a multitude of

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1 reasons. And when the new label comes out it
2 basically replaces the old label.

3 CHAIRMAN MALMUD: Yes, I understand. So,
4 that really simplifies it for the end user by
5 having one standard to adhere to.

6 MEMBER SULEIMAN: That's how I see it.

7 CHAIRMAN MALMUD: Thank you.

8 MEMBER GUIBERTEAU: Dr. Malmud, this is
9 Mickey Guiberteau. Could I ask a question, please?

10 CHAIRMAN MALMUD: Of course, Dr.
11 Guiberteau.

12 MEMBER GUIBERTEAU: This is sort of a
13 curious circumstance, but in terms of the FDA
14 labeling and requirements for a generator, as well
15 as putting some limits on the -- approving the
16 limits of the manufacturer on the moly
17 breakthrough, let's say in the instance of a
18 molybdenum-99, technetium-99 generator. If -- what
19 are the implications for off-label use in the sense
20 of medical necessity if there is not an absolute
21 limit within say the NRC regulations?

22 And just by way of example, if I were
23 to elute a generator and I had exceeded the 0.15
24 microcuries per millicurie, but felt that I had an
25 emergency procedure that needed to be performed,

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1 and I used this anyway. Would that be something
2 that would be defensible?

3 MEMBER SULEIMAN: I think that would --
4 Dr. Malmud, Orhan Suleiman again. I think that's a
5 perfect example of justified practice of medicine
6 issue. You know, you may have an emergency. This
7 may be the only generator available, this may be
8 the only test that would give you relevant
9 efficacious information, and you exercise your
10 authority as a practitioner of medicine. And I
11 would not see any problem with that at all. Our
12 oncologists, I talk to them all the time, and I
13 said so you can change your dose? I said, you know,
14 in terms of chemo or whatever or change the
15 protocols, he says oh, yes, that's -- we can do
16 that under our practice of medicine. So, even
17 though we have an official protocol that's approved
18 as part of the label, physicians -- and I'm going
19 to defer to the other physicians on the panel,
20 oncologists, my understanding is that's done often,
21 you know, if you feel that something may improve
22 for a specific patient. So, the answer to your
23 question is it would be justified.

24 MEMBER GUIBERTEAU: And do you see that
25 as a difference in culture between say such a

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1 regulation of an absolute limit in the NRC as
2 opposed to one made by the manufacturer under FDA
3 labeling?

4 MEMBER SULEIMAN: What the -- this is --
5 I, you mean, we sometimes to get policy have to go
6 through all sorts of reviews and whatever. This is
7 clearly my interpretation of our policy, but if I
8 think somebody is circumventing the regulations and
9 saying I'm doing this under practice of medicine,
10 but clearly doesn't want to comply with the safety
11 aspects of it, at that point I believe they assume
12 -- they do assume the liability themselves. And as
13 long as everything works out okay, it's acceptable.

14 Most of the manufacturers when they
15 develop a medical product they're working hand and
16 hand with the user community, with the physicians.
17 So, it's not a them or us thing. I think everybody
18 is trying to get a product out that's going to be
19 safe, that's easy to use, and there are some safety
20 standards in place. So, your example was pretty
21 easy, you know, but sometimes when people really
22 border on negligence, you know, do they want to
23 invoke -- often they'll blame some other person or
24 some -- you know, they were confused with the
25 instructions, or they'll blame one of the

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1 intermediary health professionals. But I don't
2 think -- I don't see where somebody would go
3 against what the manufacturer is recommending.

4 MEMBER GUIBERTEAU: Thank you. I just
5 wanted to clarify that in my own mind.

6 MEMBER SULEIMAN: Did I confuse or --

7 CHAIRMAN MALMUD: No, I think you
8 clarified it, at least you clarified it for me, Dr.
9 Suleiman.

10 MEMBER SULEIMAN: Thank you.

11 MEMBER GUIBERTEAU: And me, also.

12 CHAIRMAN MALMUD: Other comments?

13 MEMBER VAN DECKER: Dr. Malmud, this is
14 Bill Van Decker.

15 CHAIRMAN MALMUD: Yes, Dr. Van Decker.

16 MEMBER VAN DECKER: I think I would echo
17 some of the comments of some of the people that
18 have spoken prior. I think that we all want to look
19 at generators as a non-generic set of issues here
20 because there may be more down the line, and we
21 want them all handled in a similar level playing
22 field kind of situation. So, I think that that's a
23 good idea.

24 I think the concept of not having very,
25 very specific numbers in rulemaking space is also a

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1 wonderful concept because we know, and we're
2 watching even now how long it takes rulemaking to
3 get readjusted. So, I think we want to make sure we
4 give ourselves the leeway as the science evolves
5 and as we see how things play out.

6 I have to admit that I'm hopeful that
7 the FDA labeling concept works, or possibly not
8 knowing the fine points of the legality of some of
9 this it makes me a little nervous because, you
10 know, physicians always talking about on-label and
11 off-label, and how quickly does that change, and
12 what's the update. You know, I think I had spoken
13 to a few people about the possibility of, you know,
14 can we do some of this in appendix space rather
15 than just use FDA label or just change numbers, or
16 use -- or make it somewhat clear that the FDA's
17 labeling concept here applies only to the
18 breakthrough component of the eluate per se. So, I
19 don't know the real answers to that, but if people
20 who know more than me believe that this fulfills
21 the reality of being flexible, allowing for us to
22 move the science forward, and to make changes we
23 need to, then I trust people in that regard.

24 CHAIRMAN MALMUD: Thank you, Dr. Van
25 Decker.

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1 DR. HOWE: Dr. Malmud, this is Dr. Howe.
2 May I speak?

3 CHAIRMAN MALMUD: Yes, Dr. Howe.

4 DR. HOWE: This is kind of historical,
5 but in about 1994 we went through a very long,
6 prolonged rulemaking that was referred to as the
7 Practice of Pharmacy in Medicine Rule. And in that
8 rule, we were told by the medical community that we
9 could not hold licensees to package inserts in the
10 preparation of radiopharmaceuticals or the elution
11 of generators, nor could we hold licensees to use
12 of materials as described in the package insert.
13 And we were told that we were enforcing FDA
14 requirements when FDA was not enforcing those
15 requirements, and recognize there was more
16 flexibility. And as a result of that rulemaking, we
17 removed all requirements for our licensees to
18 follow FDA package insert. We specifically added a
19 section in Part 35, 35.7 that says nothing in this
20 part released the licensee from comply with the
21 applicable FDA, other federal and state
22 requirements governing radioactive drugs or
23 devices.

24 But we did not say, and in 2002 they
25 tried to go to plain language and say you're

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1 required to follow the FDA requirements. And we
2 very carefully went back and said no, we cannot do
3 that. We just can only say that you're not relieved
4 of following them. So, to try to in rulemaking put
5 NRC following an FDA package insert and enforcing
6 an FDA package insert would be taking us back to
7 pre-1994 situations in which the medical and the
8 pharmacy community said we were doing the wrong
9 thing. Thank you.

10 MEMBER MATTMULLER: Dr. Malmud, this is
11 Steve Mattmuller, if I could reply to that, please.

12 CHAIRMAN MALMUD: Yes, Steve.

13 MEMBER MATTMULLER: Part of the issues
14 that were raised back then were that -- were, for
15 example, indications of when what specific test a
16 radiopharmaceutical could be used for. And if it
17 wasn't in the package insert, then a licensee was
18 in non-compliance if they used it for a different
19 indication; and/or in regards to preparing a kit
20 according to the manufacturer's instructions, Orhan
21 touched on it, to sometimes change product
22 information is a costly experience for the
23 manufacturer, so even though they know the field is
24 say, for example, putting 400 millicuries of
25 technetium into a sulfur colloid kit versus the

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1 product label of 200, they know people are doing
2 quality control testing and it's a safe product,
3 but they're not going to go through the time and
4 expense to revise the product labeling to say yes,
5 you can now add 400 millicuries of per technetate to
6 a sulfur colloid kit.

7 In this discussion, I think it would be
8 important to say that the measurement for the
9 radionuclidic impurity levels shall be in
10 accordance with the generator's FDA's product
11 labeling section, as Bracco calls it, their Eluate
12 Testing Protocol. So, what we'd be recommending is
13 that just to follow that aspect in the product
14 labeling; that is, the Eluate Testing Protocol, not
15 the complete -- we're not putting out a blanket
16 statement for the whole product or package insert,
17 just that specific section on testing for
18 radionuclidic impurities in the package insert for
19 that specific generator.

20 And I'd also like to make a -- it's
21 been touched on. This is a current problem now with
22 rubidium generator in that there are more
23 restrictive testing requirements in the product
24 labeling, but NRC regulations aren't even
25 addressing it in this revision. And it could be

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1 another seven to ten years before they do accept it
2 with the current strategy that the NRC uses for
3 this type of enforcement.

4 And I think that's all I have for right
5 now. Thank you.

6 CHAIRMAN MALMUD: Thank you, Steve. So,
7 I want to thank Dr. Howe for her historical
8 perspective on this, but I'm not certain about the
9 concise point that you're making, Steve. Could you
10 just clarify it?

11 MEMBER MATTMULLER: Well, I think her
12 concern for going back -- let me put it this way.
13 If we're careful in how we word our recommendation
14 or how the regulation is worded in that testing is
15 only to the specific part in the package insert in
16 regards to eluate testing, and not to the whole
17 package insert as far as indications, or as far as
18 product preparation, then I think we're in sound
19 territory.

20 CHAIRMAN MALMUD: Thank you. Dr. Howe,
21 do you wish to respond to that?

22 DR. HOWE: I'm not sure it's that clear,
23 because I know that prior to 1994 when people were
24 testing materials for purity, they weren't using
25 the purity tests that were in the USP. And if they

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1 change -- if the manufacturer or the commercial
2 nuclear pharmacy changes how it measures the
3 breakthrough in any way from the package insert we
4 would be in a position where we would have to
5 enforce an FDA accepted package insert when FDA may
6 not. And we can't go back there.

7 CHAIRMAN MALMUD: Thank you. Dr.
8 Zanzonico?

9 MEMBER ZANZONICO: Well, it seems like a
10 regulatory dilemma but, again, the ACMUI is an
11 advisory body, and I think we should make what we
12 feel is the most appropriate recommendation. And,
13 of course, leave it to the regulator, the NRC, to
14 either accept and implement it, or not. But at
15 least our position would be on the record for the
16 benefit of the Commission. So, I think we should
17 move forward with a vote on the recommendation
18 unless there's further discussion.

19 MEMBER SULEIMAN: This is Orhan Suleiman
20 again.

21 CHAIRMAN MALMUD: Yes, Dr. Suleiman.

22 MEMBER SULEIMAN: Okay. A point of
23 clarification, the way I interpret it. We were
24 basically referring to the breakthrough limit in
25 the label. I don't think we were implying that the

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1 NRC adopt the entire label, which then could be
2 subject to all sorts of different interpretations.
3 I think here we're talking about the quantitative
4 limit as specified in the label.

5 CHAIRMAN MALMUD: Ah-hah. Dr. Zanzonico,
6 is that in agreement with your recommendation?

7 MEMBER ZANZONICO: It is now. I think
8 that's an important clarification, and I think our
9 recommendation should reflect that point.

10 CHAIRMAN MALMUD: That would be a
11 limitation to the breakthrough level in the label.
12 Who seconded your motion, Dr. Zanzonico?

13 MEMBER ZANZONICO: Well, I don't think I
14 actually made the formal motion, but I'll be happy
15 to do so.

16 CHAIRMAN MALMUD: All right.

17 MEMBER ZANZONICO: So, it'll be a bit on
18 the fly, but the motion is the following. The NRC -
19 - I'm sorry, the ACMUI recommends that the NRC
20 adopt the FDA package -- the FDA approved package
21 insert for breakthrough limits for radio isotope
22 generators.

23 CHAIRMAN MALMUD: Thank you, that's a
24 concise recommendation. Is there a second to it?

25 MEMBER MATTMULLER: I'll second it.

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1 Steve Mattmuller.

2 CHAIRMAN MALMUD: Thank you, Steve. May
3 I ask Dr. Howe if she thinks that this might fly?

4 DR. HOWE: I --

5 CHAIRMAN MALMUD: You don't want to --
6 I'm sorry, I didn't hear you.

7 DR. HOWE: Oh, Neelam will speak.

8 CHAIRMAN MALMUD: Thank you.

9 MS. BHALLA: Yes, this is Neelam Bhalla.
10 And we believe this for -- as a rule writer we have
11 been always guided that in our rules we should
12 state the limits, what the regulations are directly
13 in our regs so that a licensee is not referred to
14 or not sent somewhere else. And this is referred to
15 as incorporation by reference.

16 For example, in the Part 20 about
17 public protection or radiation exposure to the
18 members of the public, many of the things are based
19 on the ICRP or the NCRP recommendations, so we
20 don't say in our regs go to ICRP-100 and look at
21 whatever those numbers are, and that's what our
22 regulation is.

23 So, in this particular case I'm not
24 really sure if we are treading onto that wrinkle
25 where we are sending the licensee somewhere else.

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1 So, I'll be a little bit reluctant on -- and I just
2 wanted you to know about that, that we --
3 generally, we like to put whatever the regs are,
4 whatever numbers are right in our regs.

5 CHAIRMAN MALMUD: Thank you for that
6 clarification. I wanted to -- the purpose of my
7 asking for it was to have it expressed so that the
8 Committee members will understand the issue. I
9 heard another voice?

10 VICE CHAIR THOMADSEN: That is Bruce
11 Thomadsen. May I comment?

12 CHAIRMAN MALMUD: Please, Dr. Thomadsen.

13 VICE CHAIR THOMADSEN: I very much
14 appreciate the NRC trying to keep everything in the
15 one document, and I think as a user it is very
16 convenient to do so. The problem that's trying to
17 be addressed here is the ossification of the
18 recommendations even as situations change, and the
19 recommendations get out of date and actually may
20 become dangerous.

21 The question of sending the user
22 somewhere else and having them look these things up
23 is not as big of a problem here as it would be if
24 you were referring to an ICRP report to which many
25 people may not have ready access. But if you're

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1 dealing with a generator, it's assumed that you
2 also do have their package insert, and you would
3 have the recommendations that go with the package
4 insert right there before you.

5 MEMBER BAILEY: Dr. Malmud, this is
6 Darice Bailey. May I speak?

7 CHAIRMAN MALMUD: Yes, but first, Dr.
8 Thomadsen's point is well made. Okay. You're on.

9 MEMBER BAILEY: I want to add to his
10 point, NRC in their transportation rules referenced
11 Title 49 extensively and it's really difficult to
12 look them up. So, it is done in NRC rule territory
13 to reference other numbers.

14 MS. CHIDAKEL: Excuse me. This is Susan
15 Chidakel. I have been sitting here listening to
16 this discussion, and I haven't participated
17 because, to be honest, I don't know the answer. But
18 I do want to tell you that there are legal issues
19 here that are being raised that may have a definite
20 answer. It's more than just expressing an opinion
21 whether this fits within here, or fits within
22 there, whether this is like our DOT regs, or
23 whether this is like the IAEA regs, or whatever it
24 is. We have certain legal standards.

25 I, personally, do not know what they

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1 are off the top of my head, but I just want to warn
2 you, you know, opinion doesn't matter here. This is
3 something that may be dictated by what the legal
4 standards are. I just want to caution you on that.
5 You can make a recommendation that I can go back
6 and research this out, or discuss this with my
7 management and find out that this is not legally
8 permissible.

9 CHAIRMAN MALMUD: Thanks.

10 MS. CHIDAKEL: It may be. I don't know.

11 CHAIRMAN MALMUD: Thank you, Counselor
12 Chidakel. That's why I raised the issue the way
13 that I did, because I wanted the Committee members
14 to understand that our recommendation might not be
15 accepted. We don't --

16 MEMBER VAN DECKER: Dr. Malmud.

17 CHAIRMAN MALMUD: I'm sorry, who's
18 speaking?

19 MEMBER VAN DECKER: This is Bill Van
20 Decker.

21 CHAIRMAN MALMUD: Yes, I just wanted to
22 finish my sentence, which is that that's why I
23 raised the issue so that there would be an
24 understanding among the Committee members that this
25 may or may not fly. Thank you. Dr. Van Decker.

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1 MEMBER VAN DECKER: Yes. I think that,
2 you know, we're not going to solve the exact
3 wording here today. But I think that, you know, the
4 thing that has come across everyone who has spoken
5 is that we're looking for something not written in
6 stone in rulemaking space that doesn't allow us
7 dexterity to change with the times; that if we go
8 with something along the concept of FDA labeling,
9 we're really talking about only the breakthrough
10 piece and not the rest of the clinical piece of
11 this. And, you know, whether that is some other way
12 to describe what we're trying to refer to, or
13 whether that's some way to create some appendix
14 with exact numbers that fulfill the spirit of
15 what's FDA labeling in that regard, I think that
16 most of us would probably be flexible with that,
17 but we would kind of prefer to see, you know, some
18 good be done for long-term stuff. And, I guess, the
19 real proof of the pudding will be when we all see
20 the exact wording that tries to get us to where
21 we're all trying to go.

22 CHAIRMAN MALMUD: Yes, thank you. And
23 that's what we're hoping that our learned counsel
24 might be able to tackle on our behalf.

25 MEMBER SULEIMAN: Dr. Malmud.

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1 CHAIRMAN MALMUD: Yes, Dr. Suleiman.

2 MEMBER SULEIMAN: Yes. I, too -- at FDA
3 we've been told at times by our lawyers don't adopt
4 by reference. That's for general safety rules,
5 that's for like public protection or whatever when
6 you're dealing with certain types of standards.

7 These are very product-specific so
8 you're not going to be hunting for a different --
9 you should have your user manual, or your label,
10 or your instructions right there. It's no different
11 than saying you should tune up your car, but then
12 you decide, and you say all the parts have to be
13 tested, have to be 3,000 rpm at this setting. Well,
14 it's going to vary by car, so in this case each
15 generator, you know, has the manufacturer's
16 specified limit, so I think it's quite
17 prescriptive. And that way you're not stuck with
18 using a limit that may have changed.

19 CHAIRMAN MALMUD: Thank you. We do have
20 a motion before us. It's been moved and seconded.

21 MEMBER MATTMULLER: I'm sorry, could I
22 make one more comment?

23 CHAIRMAN MALMUD: Yes. Who's --

24 MEMBER MATTMULLER: I'm sorry, Steve
25 Mattmuller.

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1 CHAIRMAN MALMUD: Thank you, Steve.

2 MEMBER MATTMULLER: One other advantage
3 this strategy would have is that for a long time
4 the vast majority of moly-99 used in the U.S. came
5 from two reactors, and their HEU uranium came from
6 one supplier, the U.S. Government. We're now in a
7 transition phase moving to low-enriched uranium
8 coming from different -- a far greater web of
9 reactors all using LEU, all using our own target
10 design, and these new target designs all have new
11 target processing procedures.

12 And in addition to reactors producing
13 moly, we have new linear accelerator manufacturers
14 trying to come on line, so there could be a whole
15 new wrinkle to rating the quota of contamination in
16 our generators. And this will be identified and
17 handled by the FDA, but it's going to be -- and
18 then any subsequent would be in their package
19 insert, which by the way does come with each
20 generator when you receive it.

21 So, the way I look at this, if the NRC
22 is saying patient safety, radiation safety, I think
23 it's incumbent upon them to find a way to do it
24 this way, because to me it's unconscionable to
25 think that if a new generator gets approved, it

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1 could take seven to ten years in the typical
2 process for it to ever make it into an NRC reg.
3 Thank you.

4 CHAIRMAN MALMUD: Thank you.

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

6 CHAIRMAN MALMUD: Yes, Dr. Howe.

7 DR. HOWE: There's another process, that
8 if we get a new generator that is significantly
9 different from what we have seen in the past; in
10 other words, the moly breakthrough has to have
11 different values, we can move things into 35.1000
12 and handle those in a matter of a few months, so
13 one should not think that we need to get everything
14 into rulemaking in order to handle new products.
15 And that's what the purpose of 35.1000 is. Thank
16 you.

17 CHAIRMAN MALMUD: Thank you for
18 clarifying that. So, if we may we'll move on with
19 Dr. Zanzonico's motion. All in favor?

20 (Chorus of ayes.)

21 CHAIRMAN MALMUD: Any opposed? Any
22 abstentions?

23 (No response.)

24 CHAIRMAN MALMUD: The motion carries
25 unanimously. Thank you. Next item, Dr. Zanzonico.

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1 MEMBER ZANZONICO: Okay. I think some of
2 the remaining items will move quickly, at least I
3 hope that's the case.

4 So, this moves us on to item 5,
5 allowing Associate Radiation Safety Officers,
6 ARSOs, to be named on a medical license. And the
7 draft recommendation in our report is that the
8 ACMUI recommends that addition of ARSOs and
9 temporary RSOs be included in exemptions in the
10 same manner as AUs, ANPs, Authorized Nuclear
11 Pharmacists, and Authorized Medical Physicists. So,
12 the crux of this recommendation is to endorse the
13 inclusion of ARSOs being named on medical licenses.

14 CHAIRMAN MALMUD: That's a motion. Is
15 there a second to the motion?

16 MEMBER LANGHORST: This is Sue
17 Langhorst. I'll second that.

18 CHAIRMAN MALMUD: Thank you. Is there
19 discussion of the motion?

20 MEMBER LANGHORST: Dr. Malmud, this is
21 Sue again. I'd like to clarify that again.

22 CHAIRMAN MALMUD: Please do.

23 MEMBER LANGHORST: As you can see in the
24 draft report, these are exemptions for the Type A
25 Broad Scope licensees, and the crux of the request

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1 is that just like Authorized Users, Authorized
2 Medical Physicists, Authorized Nuclear Pharmacists
3 are named by the Radiation Safety Committee of
4 those Type A Broad Scope licensees, we'd like to be
5 able to have that same flexibility for ARSOs and
6 clarify it for temporary RSOs, also. Thank you.

7 CHAIRMAN MALMUD: Thank you. Further
8 discussion?

9 (No response.)

10 CHAIRMAN MALMUD: All in favor of the
11 motion?

12 (Chorus of ayes.)

13 CHAIRMAN MALMUD: Any opposed? Any
14 abstentions?

15 (No response.)

16 CHAIRMAN MALMUD: The motion carries
17 unanimously. Dr. Zanzonico, you're on a run. You
18 want to take --

19 MEMBER ZANZONICO: Yes, we're on a roll.
20 Yes, the next item -- this is Item 6, and it has to
21 do with -- and it really is a very minor point, and
22 I'm not even going to make a motion, but just an
23 editorial suggestion.

24 As I was reading through the proposed
25 rule, and as with all regulations it's tough

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1 sweating. I thought it might be helpful to -- that
2 it could be shortened, and I think improved by
3 eliminating redundant passages that appear
4 throughout the document, and perhaps replacing the
5 very brief, very general abstract with an Executive
6 Summary styled section that summarizes perhaps in a
7 bullet format the key changes. I think that would
8 be welcomed by the user community to present these
9 changes up front and in a very explicit format
10 rather than dispersed, or in addition to being
11 dispersed through the body of the proposed rule.
12 So, that's just a suggestion. I don't think it
13 necessitates a motion or a vote by the ACMUI unless
14 anyone objects.

15 CHAIRMAN MALMUD: I'm certain that no
16 one objects.

17 MS. BHALLA: Dr. Malmud.

18 CHAIRMAN MALMUD: Neelam.

19 MS. BHALLA: Yes, this is Neelam. I just
20 wanted to say I wholeheartedly agree that it
21 becomes a very long document, and it sounds and
22 looks very repetitious. But this is a Federal
23 Register Notice of the proposed regulations. We are
24 bound by our procedures whereby we need to follow
25 section by section what we are changing and why we

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1 are changing. So, although 100, 200, 300 and so on,
2 they are pretty much similar, but because of these
3 stipulations we need to follow that process.

4 And, also, about the -- it's very well
5 said, but the -- you know, we could do bullet form,
6 but again we are bound by our own writing style.
7 And, therefore, we hear you but that's a way we are
8 supposed to do it.

9 CHAIRMAN MALMUD: Thank you, Neelam. We
10 understand that, and that's why I suspect Dr.
11 Zanzonico made a recommendation for those of you
12 who actually draft these to do what you do best.
13 Dr. Zanzonico.

14 MEMBER ZANZONICO: Okay. Well, we're
15 really down the home stretch. There was a seventh
16 item, that was just additional general comments.
17 And really the most notable of these, in effect,
18 has been eliminated, and that had to do with the
19 separate training and experience requirements for
20 beta gamma versus alpha emitters. We really
21 addressed that in our previous discussion and the
22 previous item. And I thank Dr. Langhorst for
23 correctly pointing out that Item 7B really is no
24 longer necessary based on our earlier actions, so
25 that's been eliminated.

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1 Other than that, there are minor
2 comments in Item 7B that I don't think warrant or
3 necessitate discussion. So, I think we really have
4 hit all the conceptual points.

5 I should point out that we had and have
6 a subsequent section in the -- in our draft report
7 on --that I called Specific Comment Significant.
8 Some of these -- a number of these based on
9 clarifications from the -- based on our previous
10 teleconference and clarifications provided by the
11 NRC Staff, as well as by emails among the ACMUI
12 members, a number of these have been eliminated.
13 These have been indicated by strikethrough text.

14 And the other point I'd like to make is
15 that these Significant Specific Comments really
16 don't introduce anything new, but just reference
17 specific passages relevant to the general items
18 that have already been discussed to make sure that
19 they're consistent, the language is consistent in
20 our opinion.

21 So, again I don't think, unless anyone
22 on the Committee feels otherwise, that they warrant
23 additional discussion. Basically, these Significant
24 Comments are made to insure compatibility between
25 what we were recommending among our general items

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1 that we discussed at length already and the related
2 specific passages in the proposed rule.

3 CHAIRMAN MALMUD: Thank you. And these
4 are the items that are listed on pages 8 through
5 the end of the document.

6 MEMBER ZANZONICO: Eight through eleven.

7 CHAIRMAN MALMUD: Yes.

8 MEMBER ZANZONICO: Then -- so, again,
9 I'll -- you know, I don't want to suppress
10 discussion if there is any.

11 CHAIRMAN MALMUD: Is there any
12 discussion of these?

13 (No response.)

14 CHAIRMAN MALMUD: I hear none, so you
15 haven't suppressed anything. Move on.

16 MEMBER ZANZONICO: All right. Then the
17 last bit of -- the last item is Specific Comments
18 Minor, and these are just purely editorial, and
19 they're just suggested. These have no scientific or
20 technical substance to them. They're just a product
21 of my own compulsion, so there's absolutely no need
22 for any discussion of whether a comma should be a
23 semicolon or a colon. And that's really the balance
24 of the report.

25 I will generate a third draft based on

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1 our teleconference today and any subsequent
2 feedback I get from the Committee members. But I
3 think we're very near a final draft for submission
4 --

5 MS. BHALLA: Dr. Malmud, may I speak?

6 CHAIRMAN MALMUD: Yes, Neelam.

7 MS. BHALLA: About the Minor Comments, I
8 know you -- there are some very good suggestions,
9 for example, hyphenate the words et cetera. And,
10 again, I just want to say that we get bound by our
11 -- it's called the Administrative folks. They are
12 the ones who actually make our regulations get
13 published in the Federal Register. So, therefore,
14 there are certain requirements. I wish we had
15 indicated for this review that not be so concerned
16 with these kind of edits because ultimately it's
17 there between the NRC's writing style, and the
18 publishing document style and so on, so we do get a
19 lot of those restrictions. And, therefore -- but,
20 nonetheless, we would take a look into these, all
21 of these because, you know, considering it's a very
22 large document, I'm sure, you know, we have perhaps
23 missed on even maybe sentences here and there. So,
24 it's great to have this, but I just want you all to
25 know that we do get bound by other restrictions.

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1 CHAIRMAN MALMUD: I can assure you that
2 the members of the ACMUI recognize that, and that
3 this document is a reflection of the diligence with
4 which this Subcommittee and its members have gone
5 through the document, and recognize that some of
6 these recommendations will not be considered
7 appropriate using the verbiage the NRC uses, but
8 they are still recommendations in the best interest
9 of clarification. And we do appreciate both your
10 effort on this, which is enormous, as well as that
11 of counsel, particularly Counsel Chidakel who works
12 -- we're sure works on these things behind the
13 scenes, as well. So, we do appreciate that, but we
14 did want you to know and the members of the
15 Subcommittee wanted you to know what we thought
16 might be perhaps optimal wording, if it's
17 acceptable.

18 MS. CHIDAKEL: Thank you, Dr. Malmud.
19 This is Susan Chidakel. I very much appreciate your
20 praising me that way.

21 I also would like to mention that we
22 decided we were going to only be giving you
23 substantive and major things at this point, and we
24 realized when we gave you this draft, and I
25 realized when we gave you this draft that we have a

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1 lot of changes that we're still making to the
2 actual language, so that it's not just that we are
3 bound by certain restrictions with regard to your
4 minor comments, but some of those things may go
5 away just through editing and through fine comb
6 tothing, whatever.

7 MS. BHALLA: Yes.

8 MS. CHIDAKEL: Anyway, fine combing with
9 fine tooth. And I've already noted to Neelam, you
10 know, some of the things that are going to need to
11 be changed as far as the editorial mix, so I just
12 wanted to add that in.

13 CHAIRMAN MALMUD: Thank you. And the
14 Committee also appreciates what has been a positive
15 change, and you give us feedback when things are
16 not acceptable so that we understand why some of
17 the recommendations of the ACMUI were not
18 acceptable because that helps justify the amount of
19 effort that the Committee members put into this,
20 even when it's not accept -- even when it's not
21 finalized. So, we do thank you.

22 Dr. Zanzonico, you have taken us right
23 through this document.

24 MEMBER ZANZONICO: Yes, we have.

25 CHAIRMAN MALMUD: And it looks like it's

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1 a grand slam. And we still have a minute or two,
2 but I think we have to ask Chris who's the official
3 representative who opened the meeting if he has any
4 comments at this point, or his delegate.

5 MR. EINBERG: Yes. Thank you, Dr.
6 Malmud, Chris Einberg. Once again, I wanted to
7 thank the ACMUI and the NRC Staff here, as well,
8 for all the hard effort that everybody's put into
9 this document and to this proposed rule.

10 We went through all the comments here,
11 substantial changes were made or the
12 recommendations where changed here so the next step
13 is for Dr. Zanzonico or the ACMUI to finalize the
14 report, and then send it to the NRC Staff.

15 We cannot go through another review of
16 this because that would be deliberations, and
17 outside of FACA, or if we do so, of if there's a
18 strong feeling to do so, we would have to have
19 another public teleconference to have deliberations
20 in the public space. So, I encourage you to make
21 those revisions and get them back to us, and we
22 look forward to receiving those and trying to
23 address the comments. And Ms. Holiday here has
24 something she would like to add, as well.

25 CHAIRMAN MALMUD: Thank you, Chris.

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1 MS. HOLIDAY: I just wanted to add that
2 at this time, as Chris mentioned, we have to get
3 the finalized report from you, so you actually have
4 to vote on finalizing the report pending these --
5 the incorporation of these revisions and
6 recommendations, and since this is the only meeting
7 time to do it, I guess this would be the time now
8 that the full Committee would need to vote to
9 approve the Subcommittee report to include those
10 revisions as mentioned during this teleconference
11 to finalize the report now.

12 CHAIRMAN MALMUD: Thank you. Would the
13 Chairman please make that as a recommendation?

14 MEMBER ZANZONICO: I guess that's me.

15 CHAIRMAN MALMUD: You're the Chairman of
16 the Subcommittee.

17 MEMBER ZANZONICO: Yes. So, I make a
18 motion that the Subcommittee approve our report
19 pending incorporation of all suggested or all
20 approved revisions.

21 CHAIRMAN MALMUD: Is there a second to
22 the motion?

23 MEMBER GUIBERTEAU: Mickey Guiberteau, I
24 second this.

25 CHAIRMAN MALMUD: Thank you, Dr.

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1 Guiberteau. Any further discussion of this report
2 with all the recommendations made in these six
3 hours of conferences that we've had?

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

6 CHAIRMAN MALMUD: Dr. Langhorst.

7 MEMBER LANGHORST: I'd just like to
8 clarify that that motion is for the full Committee
9 and not just the Subcommittee?

10 CHAIRMAN MALMUD: That's correct.

11 MEMBER LANGHORST: Yes, thank you.

12 CHAIRMAN MALMUD: The motion is coming
13 from the Chair of the Subcommittee to the entire
14 Committee. That is its purpose.

15 MEMBER LANGHORST: Thank you.

16 CHAIRMAN MALMUD: Thank you for
17 clarifying that for anyone who might not have
18 understood that. Appreciate it. So, all in favor?

19 (Chorus of ayes.)

20 CHAIRMAN MALMUD: Are there any opposed?
21 We hear no opposed. Are there any abstentions?

22 (No response.)

23 CHAIRMAN MALMUD: We hear none, so the
24 Committee passes this unanimously, that's the ACMUI
25 passes this recommendation of the Subcommittee

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1 unanimously, and we thank the Subcommittee and each
2 of its members for an enormous amount of effort. We
3 spent six hours in discussing this but that's a
4 fraction of what the members of that Committee
5 spent on drafting and crafting this document, so
6 we're very appreciative of it.

7 Now, let's see. Chris and Sophie, any
8 other comments from NRC?

9 MR. EINBERG: Nothing from this end. I
10 believe that when you're ready to adjourn, you can
11 adjourn.

12 MEMBER ZANZONICO: Can I just ask one
13 point of clarification. At this point what is our
14 submission deadline for actually submitting the
15 final report to the NRC?

16 MS. HOLIDAY: I can receive that report
17 no later than March 28th.

18 MEMBER ZANZONICO: Okay, that's fine.

19 CHAIRMAN MALMUD: Very good, thank you.
20 And we're going to be meeting in April, are we not,
21 Sophie?

22 MS. HOLIDAY: Yes, sir, April 15th and
23 16th here at headquarters.

24 CHAIRMAN MALMUD: And each of the
25 members of the Committee by now should have had his

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1 or her transportation and room arrangements
2 solidified.

3 MS. HOLIDAY: Ideally.

4 CHAIRMAN MALMUD: Ideally. If any member
5 of the Committee who intends to attend the meeting
6 has not done so, I would suggest at this point that
7 you contact Sophie who might be help you to
8 expedite the arrangements. Is that fair, Sophie?

9 MS. HOLIDAY: Yes, sir.

10 CHAIRMAN MALMUD: Thank you. I think
11 everyone's arrangements are completed, but I just
12 want to make sure in case one of you has not yet
13 done so.

14 And with that, I'd like to thank
15 everyone who participated in these discussions for
16 their efforts and their wisdom in trying to achieve
17 a final document which, hopefully, will result in
18 an efficient operation all in the interest of
19 optimal patient care. So, thank you all. We look
20 forward to seeing you in April, and hearing -- and
21 the NRC receiving the draft document by March 28th.

22 MS. HOLIDAY: Final document.

23 CHAIRMAN MALMUD: Final document. Thank
24 you very much.

25 MS. HOLIDAY: Yes, sir.

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1 MR. EINBERG: Okay. Thank you very much.

2 CHAIRMAN MALMUD: Thank you.

3 MR. EINBERG: Goodbye, everyone.

4 CHAIRMAN MALMUD: The meeting is
5 adjourned. Thank you.

6 (Whereupon, the proceedings went off
7 the record at 4:45:18 p.m.)

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