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Medical Uses of Isotopes

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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, M.D.,
11 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 Representative

16 MILTON GUIBERTEAU, M.D., Diagnostic Radiologist

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

18 STEVEN MATTMULLER, Nuclear Pharmacist

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

21 JOHN SUH, M.D., Radiation Oncologist

22 ORHAN SULEIMAN, Ph.D., FDA Representative

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

24 LAURA WEIL, Patients' Rights Advocate

25 JAMES WELSH, M.D., Radiation Oncologist

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PAT ZANZONICO, Ph.D., Nuclear Medicine Physicist

NRC STAFF PRESENT:

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

CHRISTIAN EINBERG, Designated Federal Officer

ASHLEY COCKERHAM, Alternate Designate Federal
Officer, ACMUI Coordinator

SOPHIE HOLIDAY, Alternate ACMUI Coordinator

NEELAM BHALLA, FSME/DILR/RPMB

SUSAN CHIDAKEL, OGC/GCLR/RMR

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

ED LOHR, FSME/DILR/RPMB

DEBBIE PISKURA, FSME/DMSSA/RMSB

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

NRC REGIONAL STAFF PRESENT:

JACKIE COOK, Region IV

ROBIN ELLIOTT, Region I

SARA FORSTER, Region III

DENNIS O'DOWD, Region III

LESTER TRIPP, Region I

MEMBERS OF THE PUBLIC PRESENT:

KEITH BROWN, University of Pennsylvania

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1 SUE BUNNING, Society of Nuclear Medicine and
2 Molecular Imaging

3 DAWN EDGERTON, Council for Certification in
4 Cardiovascular Imaging

5 LYNNE FAIROBENT, AAPM

6 KAREN LANGLEY, University of Utah

7 RALPH LIETO, St. Joseph Mercy Hospital

8 ANDREW MCKINLEY, American Society of Nuclear
9 Cardiology

10 MICHAEL PETERS, American College of Radiology

11 MICHAEL STEPHENS, Florida Bureau of Radiation
12 Control

13 CINDY TOMLINSON, American Society for Radiation
14 Oncology

15 MICHAEL WELLING, Virginia Department of Health

16 GARY E. WILLIAMS, Department of Veteran
17 Affairs, National Health Physics Program

18
19
20
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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 Commission.

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1 NRC, and it may also be transcribed or recorded by
2 others.

3 The meeting was announced in the February
4 1st, 2012 edition of the Federal Register, Volume 78,
5 page 7465, and is a continuation of teleconference
6 meeting that was held on last Tuesday, March 5th, 2013.

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

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

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

22 CHAIRMAN MALMUD: Here.

23 MR. EINBERG: Dr. Bruce Thomadsen, Vice
24 Chairman, Therapy Medical Physicist.

25 VICE CHAIR THOMADSEN: Here.

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1 MR. EINBERG: Ms. Darice Bailey, State
2 Government Representative.

3 MEMBER BAILEY: Here.

4 MR. EINBERG: Dr. Mickey Guiberteau,
5 Diagnostic Radiologist.

6 MEMBER GUIBERTEAU: Here.

7 MR. EINBERG: Dr. Sue Langhorst, Radiation
8 Safety Officer.

9 MEMBER LANGHORST: Here.

10 MR. EINBERG: Mr. Steve Mattmuller, Nuclear
11 Pharmacist.

12 MEMBER MATTMULLER: Here.

13 MR. EINBERG: Dr. Christopher Palestro,
14 Nuclear Medicine Physician.

15 MEMBER PALESTRO: Here.

16 MR. EINBERG: Dr. John Suh, Radiation
17 Oncologist.

18 MEMBER SUH: Here.

19 MR. EINBERG: Dr. Orhan Suleiman, FDA
20 Representative.

21 MEMBER SULEIMAN: Here.

22 MR. EINBERG: Dr. William Van Decker,
23 Nuclear Cardiologist. Dr. William Van Decker, Nuclear
24 Cardiologist? Okay.

25 Ms. Laura Weil, Patient's Rights Advocate.

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1 MEMBER WEIL: Here.

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

4 No, moving on. Dr. Pat Zanzonico, Nuclear
5 Medicine Physicist.

6 MEMBER ZANZONICO: Yes.

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

9 I now ask the NRC Staff members who are
10 present to identify themselves.

11 MS. HOLIDAY: Sophie Holiday, FSME.

12 MR. WHITE: Duncan White. I'm the Branch
13 Chief for the Agreement State Program Branch in FSME.

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

15 MS. BHALLA: Neelam Bhalla, FSME.

16 MS. CHIDAKEL: Susan Chidakel, OGC.

17 MR. EINBERG: Okay. For the people that are
18 on the line from Headquarters can you please identify
19 yourselves.

20 DR. ZELAC: Ronald ZELAC, FSME.

21 MR. EINBERG: Could you repeat that for the
22 court reporter?

23 DR. ZELAC: Ronald ZELAC, FSME.

24 MR. EINBERG: Thank you.

25 MS. PISKURA: Debbie Piskura, FSME.

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1 MS. COCKERHAM: Ashley Cockerham, FSME.

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

5 MS. ELLIOTT: Robin Elliott, Region I,
6 DNMS.

7 MR. TRIPP: Lester Tripp, DNMS.

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

11 MS. FORSTER: Sara Forster.

12 MR. EINBERG: Okay. Can you please repeat
13 that?

14 MS. FORSTER: Sara Forster.

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

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

18 Next I'd like to identify members of the
19 public who notified us that they would be participating
20 on the teleconference. When I call your name please
21 answer that you're present. Keith Brown, University
22 of Pennsylvania.

23 MR. BROWN: Here.

24 MR. EINBERG: Sue Bunning, Society of
25 Nuclear Medicine and Molecular Imaging.

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1 MS. BUNNING: Here.

2 MR. EINBERG: William Davidson, University
3 of Pennsylvania. Casey Deitrich, CQ Transcriptions.
4 Dawn Edgerton, Council for Certification in
5 Cardiovascular Imaging.

6 MS. EDGERTON: Here.

7 MR. EINBERG: Lynne Fairobent, American
8 Association of Physicists in Medicine.

9 MS. FAIROBENT: Here.

10 MR. EINBERG: Norman LaFrance, Jubilant
11 Draxlmage, Incorporated. Karen Langley, University of
12 Utah.

13 MS. LANGLEY: Present.

14 MR. EINBERG: Ralph Lieto, St. Joseph Mercy
15 Hospital.

16 MR. LIETO: Present.

17 MR. EINBERG: Magali Lurquin, Jubilant
18 Draxlmage. Andy McKinley, American Society of Nuclear
19 Cardiology.

20 MR. MCKINLEY: Here.

21 MR. EINBERG: Tamara Mills, Jubilant
22 Draxlmage. Mike Peters, American College of Radiology.

23 MR. PETERS: Here.

24 MR. EINBERG: Joe Rodgers, Paragenics
25 Corporation. Gloria Romanelli, American College of

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1 Radiology. Michael Sheetz, University of Pittsburgh.

2 Michael Stephens, Florida Bureau of Radiation Control.

3 MR. STEPHENS: Here.

4 MR. EINBERG: Cindy Tomlinson, American
5 Society for Radiation Oncology.

6 MS. TOMLINSON: Here.

7 MR. EINBERG: Michael Welling, Virginia
8 Department of Health.

9 MR. WELLING: Here.

10 MR. EINBERG: Gary Williams, Department of
11 Veterans Affairs, National Health Physics Program.

12 MR. WILLIAMS: Here.

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

15 MR. McDERMOTT: Yes, this is Brian
16 McDermott, Director of the Division of Material Safety
17 and State Agreements in FSME.

18 MEMBER WELSH: James Welsh with the ACMUI.

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

20 As you know, we have a bridge line
21 available for this call, and that phone number is
22 (888)864-0940. The pass code to access the bridge line
23 is 34081#.

24 At this time, I ask that everyone on the
25 call who is not speaking to place their phones on mute.

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1 If you do not have the capability to mute your phone,
2 please press *6 to utilize the conference line mute
3 and unmute functions. I would ask everyone to exercise
4 extreme care to insure that the background noise is
5 kept to a minimum as any background sounds can be very
6 disruptive on a conference call this large.

7 This is a Category I public meeting. This
8 is an open public observatory meeting, but is
9 non-participatory. Members of the public may listen
10 to the meeting. The draft proposed expanded Part 35
11 Rule is considered pre-decisional and has not been
12 transmitted to the NRC Commission for a vote. The rule
13 is anticipated to be sent to the Commission in the late
14 summer of 2013.

15 After Commission approval, the rule will
16 be published in the Federal Register and members of
17 the public will be given a 90-day comment period pending
18 Commission approval versus the typical 75-day comment
19 period.

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

22 CHAIRMAN MALMUD: Thank you, Chris. If I
23 may, we have one item to present prior to the agenda
24 and that is a comment from Duncan White who will brief
25 us on an issue that was raised by members of the

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1 Committee and which he will address for us. Please,
2 Duncan White.

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

6 My Branch has -- one of its primary
7 responsibilities is to review all Agreement State
8 regulations for compatibility, and we do this for all
9 37 Agreement States. And as part of that process, we
10 look at a wide range of regulations including the
11 medical ones and make determinations if the States'
12 regulations are compatible with NRC regulations.

13 In addition to that, as part of the NRC
14 rulemaking process, I serve as a co-chair to what's
15 called Standing Committee on Compatibility. When draft
16 rules are made available for comment, as you know, they
17 are provided to the states, and also at that time our
18 Committee also takes a look at it with the objective
19 to insure that the proposed rule and the compatibility
20 determinations made in that proposed rule are
21 consistent with the Agency's Policy Statement on
22 adequacy and compatibility. We also look to ensure that
23 it's consistent with other rules and regulations that
24 are already in existence out there.

25 This group has been in place for about four

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1 years now, and we've looked at a number of different
2 rules, hopefully to ensure that there's a consistent
3 application of the Policy Statement.

4 Again, as with any proposed rule, the
5 Committee had an opportunity to look at the proposed
6 rule that you're all looking at right now. We met
7 yesterday. We discussed the draft rule yesterday with
8 all five members of the Committee, also Neelam Bhalla
9 who was the Project Manager for that, and Ed Lohr
10 participated in that discussion.

11 One of the things that we did focus on was
12 the specific question that is in the proposed rule to
13 ask about is the Compatibility Category for the Section
14 35.3045 Report and Notification of a Medical Event.
15 Again, the draft FRN will ask, and again this will be
16 out for public comment, get people's view on the
17 compatibility with Category B, or Compatibility
18 Category C. And I think as written in the proposed rule
19 right now it provides a balanced view of why maybe you
20 think it would be a B, or you think it would be Category
21 C.

22 The Committee did discuss this at length
23 and unanimously indicated back to -- and we'll be
24 writing this in the memo. We unanimously agreed that
25 we felt it should be Compatibility Category C. And the

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1 reason we came to that conclusion is for a couple of
2 different reasons.

3 For some -- for a section of the
4 regulations to be Compatibility Category B it has to
5 have significant trans-boundary implications. And for
6 Compatibility Category C it has to be -- the
7 requirements for that, is has to -- that the absence
8 of the compatibility designation, if it's Compatibility
9 Category C it cannot create a gap, duplication, or
10 anything like that in the national program.

11 And after our discussions with that, we
12 felt it did not meet the definition of significant
13 trans-boundary implications, and certainly it did
14 qualify as Compatibility Category C.

15 Again, one of the things the group did
16 point out and did discuss at length is that -- made
17 it very clear, if the final rule, for example, is
18 Category C, the states would still be required to report
19 the source strength criteria to the NRC. They would
20 be required to do so. That is considered part of the
21 essential objective of that rule, and the states must
22 report that.

23 Under Category C they would have the option
24 of requiring their licensees to report the dose-base
25 criteria in addition to that, but they would still be

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1 required, like NRC licensees are required to report
2 the source strength of the activity-based quantity.
3 They could also do this additional one.

4 The other reason is that the important
5 aspect of the Policy Statement is to insure that there's
6 flexibility given to the states to adhere to local
7 conditions and local requirements. There are -- we are
8 aware of some states that do collect information on
9 medical events, misadministrations. They call them
10 different things with regard to collecting additional
11 information for their -- for individual states.

12 Some states have specific legal
13 requirements that they must meet. There's a state law
14 that they must adhere to, and that's why they collect
15 the information.

16 We had a similar situation in the past
17 where we had a different rule where, again, the NRC
18 changed the regulation, specifically changed the
19 compatibility requirements from Category C to Category
20 B, and the states -- it caused a great deal of conflict
21 with the states because the states had existing programs
22 in place. And when you go to Category B, you basically
23 require the states to have the identical, exactly the
24 same, and I mean identical, I mean word for word exactly
25 the same requirements. And there were states that had

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1 existing programs for -- it involved registration of
2 general license devices. And some states took -- some
3 states eventually decided to petition the NRC, and
4 eventually that was -- about eight or nine years later,
5 it was returned to Category C.

6 Again, the Commission recognized that the
7 states need that flexibility for the local situation
8 the states were in. And, again, it wasn't a one-size
9 fits all.

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

25 Again, that's what Compatibility Category

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1 C would mean. Again, if it was C, they may ask for the
2 dose-base, and that's their prerogative to do so. And
3 they need to ask for additional information. Again,
4 that's their prerogative to do so.

5 If it was a B, again, they would not be
6 able to collect any other information, and that may
7 put them in conflict with their state laws, and their
8 state requirements. So, again, this was the basis for
9 the Committee's decision to endorse the Compatibility
10 Category C with regard to this.

11 Again, our recommendations will be
12 forwarded to Neelam Bhalla, and they will be part of
13 the Commission paper that will go up as well as I
14 understand the ACMUI's views, too, on that.

15 So, with that are there any questions for
16 me?

17 CHAIRMAN MALMUD: This is Dr. Malmud. Are
18 there any questions?

19 MEMBER ZANZONICO: This is Pat Zanzonico.
20 I have a question, if I may.

21 CHAIRMAN MALMUD: Please do.

22 MEMBER ZANZONICO: I gather in the past rule
23 on medical events for permanent implant brachy one of
24 the criteria was a dose differing from the prescribed
25 dose that would have resulted in an effective dose of

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1 5 rem, a normal organ dose of 50 rem, et cetera, et
2 cetera.

3 If this were Compatibility C would the
4 states have the option, the Agreement States have the
5 option, for example, of retaining those dose-based
6 criteria?

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

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

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1 effect, it seems to be undermining that key objective
2 of sensitively and specifically capturing clinically
3 significant events.

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

13 MEMBER WELSH: This is Dr. Welsh, if I might
14 contribute.

15 CHAIRMAN MALMUD: Please do.

16 MEMBER WELSH: Yes, I would agree with what
17 Dr. Zanzonico has just stated, that Compatibility C
18 wherein States are still allowed to impose what the
19 Subcommittee feels were inappropriate criteria for
20 medical events would seriously undermine many years
21 of very intensive hard work that has been done to
22 communicate to the NRC at the very highest levels the
23 inappropriateness of the previous definitions. And the
24 key point regarding the inappropriateness of the
25 previous definitions was the use of dose as criteria.

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1 And, therefore, it just does not seem to make sense
2 that what has been almost conclusively and unanimously
3 felt to be an inappropriate medical event definition,
4 i.e., use of dose as a criteria, should really not be
5 permitted anymore because that does go back to the use
6 of clinically irrelevant or clinically inappropriate
7 definitions for medical events. And we would not have
8 gained a whole lot after all this time and effort if
9 the states were to continue to use dose inappropriately
10 as Compatibility C might enable.

11 VICE CHAIR THOMADSEN: Dr. Malmud.

12 CHAIRMAN MALMUD: Yes.

13 VICE CHAIR THOMADSEN: This is Bruce
14 Thomadsen, if I may comment.

15 CHAIRMAN MALMUD: Please do.

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

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

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

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

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

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

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

21 I'm also -- I think it's -- in fact, it's
22 a question that's in there, and public input on that
23 I think will be very good, and very, very helpful just
24 to hear -- get a full airing of this discussion. I think
25 that would be very, very good.

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

3 CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

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

7 CHAIRMAN MALMUD: That's a question for
8 anyone on the conference call.

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

20 CHAIRMAN MALMUD: Thank you. Are there
21 other comments?

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

25 CHAIRMAN MALMUD: Yes.

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

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

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

22 CHAIRMAN MALMUD: Thank you. Further
23 comments or discussion?

24 MEMBER ZANZONICO: This is Pat Zanzonico.
25 I understand and empathize with the requirement of the

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

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

17 MR. WHITE: This is Duncan White, again.
18 There have been occasions where the NRC Commission has
19 approved rules and regulations which may run counter
20 to existing state laws or state regulations, and they
21 are required -- they will be required to change them.
22 That has happened in the past. Again, the Commission
23 once it votes and approves the final rule with the final
24 Compatibility determination, that's the final
25 determination and we go forward from that. And, again,

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1 pending a petition or some other mechanism to change
2 the rules, the states are to find a way to comply with
3 the Compatibility Category. And if that means changing
4 law, that means changing law.

5 CHAIRMAN MALMUD: Thank you for clarifying
6 that for us. Other comments? If not, may we move on
7 having covered the subject that Duncan White presented
8 to us?

9 MR. WHITE: Thank you, Dr. Malmud, for the
10 opportunity talk to the Committee.

11 CHAIRMAN MALMUD: You're welcome. Thank you
12 for helping to clarify the issue. The issue is not
13 resolved but it is clarified, and we appreciate the
14 clarification.

15 MEMBER ZANZONICO: Dr. Malmud, this is Pat
16 Zanzonico again. I know there was a sort of a preamble
17 so to speak to the actual teleconference, but would
18 it be appropriate at this point to either have a vote
19 or re-vote on the recommendation with regard to Cat
20 B versus Cat C as it currently appears in our draft
21 report?

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

24 MEMBER ZANZONICO: Well, if I may, I would
25 like to make the motion so that we can move past this

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1 issue on to the subsequent issues.

2 CHAIRMAN MALMUD: The Chair welcomes your
3 making such a motion.

4 VICE CHAIR THOMADSEN: And this Bruce
5 Thomadsen. I will second that.

6 CHAIRMAN MALMUD: There has been a motion
7 moved and seconded. Is the motion clear to those who
8 are on the conference call?

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

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

13 MEMBER ZANZONICO: This is Pat Zanzonico.
14 I can read it. And the motion is that the ACMUI
15 recommends that the draft rule redefining medical
16 events in permanent implant brachytherapy be designated
17 as Compatibility Category B.

18 MEMBER LANGHORST: Thank you. This is Sue
19 Langhorst. It's clear now.

20 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico
21 and Dr. Langhorst. Other -- is there anyone else who
22 requires clarification of the motion? If not, is there
23 a discussion of the motion?

24 (No response.)

25 CHAIRMAN MALMUD: Hearing no further

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1 discussion, all those in favor please say aye.

2 (Chorus of ayes.)

3 CHAIRMAN MALMUD: Are there any opposed?

4 MEMBER BAILEY: Yes.

5 CHAIRMAN MALMUD: Dr. Langhorst, is that
6 you?

7 MEMBER BAILEY: Darice Bailey.

8 CHAIRMAN MALMUD: Oh, thank you.

9 MEMBER BAILEY: Thank you.

10 CHAIRMAN MALMUD: One opposed. Any
11 abstentions?

12 MEMBER GUIBERTEAU: Yes, this is Mickey
13 Guiberteau. I abstain.

14 CHAIRMAN MALMUD: And Dr. Guiberteau
15 abstains; otherwise, the motion carries. So, the motion
16 carries with one abstention and one negative vote. Both
17 from Texas, I assume.

18 MEMBER GUIBERTEAU: I guess that's right.

19 CHAIRMAN MALMUD: You truly are the Lone
20 Star State. Thank you, and thank you, again, Duncan
21 White, for your presentation.

22 That being the case, we'll move on to the
23 agenda, and the agenda belongs to a very hardworking
24 Chairman of the Subcommittee, Dr. Zanzonico.

25 MEMBER ZANZONICO: Okay, thank you very

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1 much. And I also have to acknowledge all of the time
2 and effort of my fellow Subcommittee members, and other
3 members of the ACMUI. There's been a lot of give and
4 take, and really a lot of thoughtful discussion and
5 exchanges among the members of the Subcommittee and
6 the ACMUI as a whole. And I think we can all be proud
7 of our effort.

8 We had covered from our draft report, and
9 since last week's teleconference a second draft has
10 been generated based on the teleconference, and based
11 on subsequent exchanges. And the in-progress as I call
12 it second draft was circulated to all the members of
13 the ACMUI and earlier today to the NRC. And we had
14 basically addressed up to this point the first three
15 items in our draft report, the medical event definition
16 for permanent implant brachytherapy, the training and
17 experience requirements for Authorized Users and other
18 authorized professionals, and the extending
19 grandfathering to certain certified individuals per
20 the Ritenour petition.

21 So, those three issues, as I say, had been
22 addressed and we had votes on the motions and so forth.
23 Unless anyone has a need or desire to revisit those
24 issues, I would move on to the next item in our draft,
25 Item 4, which has to do with measuring molybdenum

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1 contamination in generators. But before I do that, is
2 there any further comment or discussion of any of the
3 first three items?

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

6 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

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

9 MEMBER ZANZONICO: Is that correct? Okay,
10 I guess I was too optimistic.

11 MEMBER LANGHORST: Sorry about that.

12 MEMBER ZANZONICO: No, thank you for
13 correcting me. And you are right, you are correct. And
14 I should have recollected that from our most recent
15 emails. So, let me return then to Item 2D.

16 This has to do with the training and
17 experience requirements for different classes of
18 radionuclides or radiopharmaceuticals based on their
19 radiation emissions. And in the proposed rule, it's
20 proposed to include a category for alpha-emitting
21 radiopharmaceuticals as well as beta gamma emitters.
22 And my feeling and the feeling of others, though not
23 necessarily everyone on the Subcommittee as well as
24 the ACMUI was that that was not necessary or desirable,
25 specifically that an Authorized User who has the

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1 requisite training and experience to use beta and gamma
2 emitters therapeutically already has the appropriate
3 training and experience to use alpha emitters, as well.
4 And there was no significant difference in these
5 different kinds of decay properties to warrant this
6 kind of parsing of authorization.

7 And then there was some -- there's been
8 continued discussion by email among the members of the
9 Subcommittee and the ACMUI, but one analogy that came
10 to mind as I was discussing with some of my fellow
11 Subcommittee members was in the field of medical
12 oncology where medical oncologists are -- many medical
13 oncologists are sub-boarded as I understand in that
14 specialty, and in that case a medical oncologist can
15 and likely would use a wide variety of anti-cancer drugs
16 which have very, very different mechanisms of action,
17 very different organ toxicities and so forth; yet, being
18 qualified to perform chemotherapy-based treatment of
19 cancer, they have the necessary training and experience
20 to do that across all anti-cancer agents. And I think
21 that's actually a fair analogy, a good analogy to using
22 say alpha emitters therapeutically versus gamma beta
23 emitters therapeutically versus auger electron
24 emitters therapeutically. That's not to say they might
25 not need additional training on a specific

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1 radiopharmaceutical but yet they have the basic body
2 of knowledge to be able to integrate a new
3 radiopharmaceutical regardless of its decay properties
4 into their practice, into their management of patients;
5 just as a medical oncologist might require additional
6 training with a new anti-cancer agent, but yet they
7 have the basic underlying training and experience to
8 safely and effectively incorporate that into their
9 practice.

10 So, on that basis among other
11 considerations I personally -- my personal
12 recommendation would be that this introduction of a
13 new category of Authorized User, in effect, based on
14 alpha emission is really unnecessary, unwarranted, and
15 so forth. And with that, I would open this point up
16 for discussion by the members of the Committee.

17 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.

18 MEMBER WEIL: This is Laura Weil. Can I make
19 a comment related to Dr. Zanzonico's statement?

20 CHAIRMAN MALMUD: Certainly.

21 MEMBER WEIL: So, if a purpose of regulation
22 is public protection, I think we can all agree that
23 that is the case. At present it might be sensible to
24 include radium-223 since that's the case in point we're
25 after here with a larger group of radionuclides for

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1 licensing purposes. But I'm posing the possibility that
2 future use of not yet identified alpha-emitting
3 radiopharmaceuticals with characteristics that are
4 very different from radium-223, those other alpha
5 emitters might need different equipment skills and
6 knowledge. And alpha emitters are different enough,
7 they have different radio biology, they have different
8 contamination concerns. They need to be managed
9 differently enough to, I believe, require different
10 authorizations.

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

22 VICE CHAIR THOMADSEN: Dr. Malmud.

23 CHAIRMAN MALMUD: Yes, Dr. Thomadsen.

24 VICE CHAIR THOMADSEN: May I comment on
25 that?

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1 CHAIRMAN MALMUD: Please do.

2 VICE CHAIR THOMADSEN: If we look at
3 possible alpha emitters we really do not see any
4 isotopes that are going to behave very differently than
5 the radium-223. They just do not exist as possibilities
6 for radiotherapy treatment.

7 As we look at the current isotopes that
8 are being used in their clinical forms, we see that
9 biologically the colloidal P-32 is very different than
10 intravascular P-32 for polycythemia vera. They just
11 are biologically completely different animals.

12 If we look at the betas from the P-32 and
13 compare them with the betas from any OJ emitter,
14 biologically they're incredibly different. Their
15 relative biological effectiveness are incredibly
16 different also. As we look at the radioimmune carriers
17 in which we would put any of these radio isotopes and
18 compare their biology with the IVP-32, it's incredibly
19 different.

20 All the time we're looking at these
21 radiopharmaceuticals, each one is very different and
22 unique in its own right. That's why it exists. That
23 is part of what learning in the residency how to adapt
24 to these types of differences is very important in the
25 training, but looking at the potential for the alpha

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1 emitters that much difference is no greater than the
2 difference between all the existing radionuclides.

3 CHAIRMAN MALMUD: Thank you, Dr. Thomadsen.

4 Ms. Weil, does that reassure you at all?

5 MEMBER WEIL: Reassuring is perhaps not the
6 right word. Perhaps I might say then that categorization
7 by class of emitter is less than perfect, but I'm having
8 difficulty with the blanket licensure for all
9 Authorized Users.

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

12 CHAIRMAN MALMUD: Yes, Dr. Suleiman.

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

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1 how their -- the actual chemical, the radio label
2 chemical may behave very different chemically
3 biologically, but in terms of outside the body, that
4 should be more than adequately covered by appropriate
5 vendor training.

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

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

24 CHAIRMAN MALMUD: Yes, Dr. Welsh.

25 MEMBER WELSH: So, what I've heard from

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

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

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

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

10 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

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

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

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1 Authorized Users get, that covers the full breadth,
2 as Pat was talking about in regard to medical oncology
3 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 fine
7 into those two different categories that then I as a
8 radiation safety officer have to tally up who's got
9 what parenteral administrations, and if they're already
10 an Authorized User do they have to go back and get it?
11 And it just -- that's, I think, an unnecessary
12 bookkeeping requirement that splitting them would
13 impose upon us. Thank you.

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

17 MEMBER WEIL: I certainly am grateful for
18 the clarification of other members of the Committee's
19 comments, but I'm concerned that staff seemed to have
20 a very different perspective about this. And given that
21 there's very little input from Staff in this process,
22 I am -- I don't feel that I'm hearing both sides of
23 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 very
3 comfortable, Laura, with the consensus that appears
4 to be developing in terms of the safe handling and
5 administration across a broad spectrum of alpha
6 emitting radio isotopes that there really is little
7 in the way of safety differential in terms of the
8 patient.

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

22 So, there is a balance here. I do
23 understand your concerns, but I think in terms of access
24 to care and in terms of the radiation safety uniformity
25 pretty much between alpha emitters and gamma emitters

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1 as we know them, that this -- the way this has been
2 stated by the Committee makes a lot of sense.

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

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

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

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

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

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1 be the case for alpha emitting therapy or any other
2 form of radionuclide therapy.

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

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

22 The ACMUI recommends that the work
23 experience for parenteral administrations under
24 Sections 35.390 (b) (1) (2) (g), and 35.396 not be
25 separated between parenteral administrations of a beta

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1 gamma emitting radiopharmaceutical versus an alpha
2 emitting radiopharmaceutical as proposed in the
3 proposed rule. So, I would make a motion that we vote
4 on that recommendation.

5 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
6 That is a motion. Is there a second to the motion?

7 MEMBER GUIBERTEAU: Second.

8 CHAIRMAN MALMUD: Who seconded, please?

9 MEMBER GUIBERTEAU: Mickey Guiberteau.

10 CHAIRMAN MALMUD: Thank you, Dr.
11 Guiberteau. The motion has been moved and seconded.
12 Is there further discussion?

13 (No response.)

14 CHAIRMAN MALMUD: Hearing none, all in
15 favor of the motion?

16 (Chorus of ayes.)

17 CHAIRMAN MALMUD: Any opposed? Any
18 abstentions?

19 MEMBER WEIL: Yes, this is Laura Weil. I
20 will abstain.

21 CHAIRMAN MALMUD: Thank you. So, the motion
22 passes with one abstention. Thank you, Dr. Zanzonico.

23 MEMBER ZANZONICO: Okay, thank you.

24 So, lest I skip over another item, and I
25 thank Dr. Langhorst for keeping us on track, the next

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1 item would then be Agenda Item 3. What I would like
2 to do is read the motion as it appears in our draft
3 report and then solicit comments. There may or may not
4 be, so let me read the recommendation.

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

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

18 CHAIRMAN MALMUD: Are there any comments?

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

21 CHAIRMAN MALMUD: Absolutely. Thank you.

22 MS. BHALLA: Yes, the entire Ritenour
23 petition is based on grandfathering an individual. And
24 right now under 35.57 in the regs it starts that any
25 individual who's identified on a license, and that

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1 identification goes back to 2005 time frame, that person
2 need not comply with the training and experience
3 requirements of the current regulations. So, therefore,
4 that date is very important because after that date,
5 after the 2005 revision the boards had to meet certain
6 requirements to meet with the new training and
7 experience requirements.

8 So, therefore, when the petition came,
9 Ritenour's petition came, the petition was that there
10 were individuals who met the old Subpart J requirements
11 in terms of for the medical physicists and for the RSOs,
12 but they didn't have an opportunity to be named on a
13 specific license for a whole lot of different reasons.

14 So, when NRC reviewed the petition, agreed
15 with the petitioner that yes, the way the rule got
16 written it did compromise some of those people who were
17 boarded, who met our Subpart J requirements, but just
18 because they were not named on a license as of that
19 date they now had to meet the new requirements.

20 So, therefore, when we have now amended
21 this rule to take care of all those individuals and
22 to recognize their board certifications as of the old
23 Subpart J, we need to leave that date. It's very
24 important. Otherwise, if there is no date, then the
25 people who are meeting the new boards, they're already

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1 -- they would be -- they would not need this -- they
2 would not fall into the old Subpart J. So, therefore,
3 the 2005 date is crucial, and we would keep it.

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

6 CHAIRMAN MALMUD: Identify yourself.

7 MR. LOHR: I'm sorry, this is Ed Lohr. I
8 believe what's being identified is the individuals who
9 are boarded after 2005, but before the NRC has
10 recognized that board. I believe the comment was made
11 that all boards regardless of when should be recognized.
12 And the Ritenour petition did not address that, as
13 Neelam has been saying. It addressed those prior to
14 2005 when the NRC was recognizing those boards. But
15 there is a so called gap, if you will, between the time
16 from 2005 until the boards were recognized under the
17 new process. And I believe that's what has been brought
18 up by Dr. Zanzonico, but I didn't want to put words
19 in his mouth. I just want to make sure that's what he's
20 talking about.

21 MEMBER ZANZONICO: This is Pat Zanzonico.
22 That's basically it. There does seem to be a gap here
23 that's problematic, or potentially problematic.

24 CHAIRMAN MALMUD: Dr. Zanzonico, is that
25 what you were addressing?

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1 MEMBER ZANZONICO: Yes.

2 CHAIRMAN MALMUD: Thank you.

3 MEMBER ZANZONICO: This is Pat Zanzonico
4 again. I guess my question is, and I apologize for being
5 dense on this point. I still don't quite understand
6 what the problem would be with the ACMUI recommendation
7 as I verbalized it. In other words, making the date
8 of recognition of a board by the NRC irrelevant. I don't
9 -- I still don't quite understand what regulatory issue
10 that would introduce.

11 CHAIRMAN MALMUD: Neelam, could you address
12 that?

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

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

25 CHAIRMAN MALMUD: Excuse me, this is Dr.

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1 Malmud. Would you please identify yourself for the
2 Committee.

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

5 CHAIRMAN MALMUD: Thank you.

6 MS. CHIDAKEL: And I don't think that -- I
7 think there's a disconnect in what you're seeing in
8 this rule. I don't think your concern is in the -- what's
9 in the rule is not going to -- your concern doesn't
10 connect with this.

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

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

22 The reason the date is in there is because
23 in 2005, those boards were no longer recognized, so
24 we want to make clear that after 2005, you know, these
25 new individuals coming in are going to have to have

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1 certification by the boards that are now being
2 recognized under the new rule. Am I making sense? Am
3 I making this clear to you? So, it's not impacting -- I
4 guess I don't see the problem. I read your
5 recommendation several dates that the date of
6 recognition should not impact individuals seeking to
7 be named. I don't see where the date of recognition
8 of a board has anything to do with what we're doing
9 here in this new rule. We don't say anything about the
10 date of recognition of a board.

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

19 CHAIRMAN MALMUD: I think you have
20 clarified it. What do other members of the Committee
21 feel?

22 MEMBER ZANZONICO: This is Pat Zanzonico.
23 I think you've clarified it, as well. My concern -- and,
24 again, I think you clarified it, was that individuals
25 who might have been board certified -- whose board may

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1 -- who may be certified by a board which was recognized
2 after this date somehow fell through the cracks. But
3 you're assuring me that's not the case.

4 MS. CHIDAKEL: No. The whole idea is to
5 -- using 2005 is the point where the new rule came into
6 effect and we had boards now that had to come in for
7 certification. Donna-Beth, did you want to add
8 something?

9 DR. HOWE: Yes, this is Dr. Howe. When we
10 changed the rule in 2005, all the boards had to come
11 in to be recognized. And there were new criteria for
12 them to be recognized. Not all of the boards met the
13 new criteria on the date that the rule came into effect
14 and many boards -- I won't say many, but a number of
15 boards had to change their program so they could comply
16 with the new criteria for recognizing the board. And
17 that may have taken a year, two years, or longer, so
18 there are boards that were continuing to issue
19 certificates but they did not meet the NRC requirements
20 2005 until the date that they're recognized on our
21 website, which was -- an individual date was negotiated
22 for each board.

23 So, in some cases for the nuclear pharmacy
24 board, it's totally moot. We recognize the nuclear
25 pharmacy board from almost day one. There was no gap.

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1 For other boards like nuclear medicine they had
2 diplomates that didn't receive training under
3 Authorized Users, and our regulation said we could only
4 recognize those that had training under Authorized
5 Users, so there became a distinction between different
6 board certifications whether they were in the U.S.,
7 or outside of the U.S. So, we have specific certificates
8 that are recognized because the process that goes with
9 those certificates are recognized by NRC.

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

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

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

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

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

20 There are a number of other boards that
21 did not do that, and did not want to go back, so they
22 are recognized from a specific date forward. I think
23 the Health Physics Board is an example where they're
24 recognized at a certain date that's not 2005 because
25 they did not want to go back and verify the training

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1 and experience met our criteria even though their
2 criteria was much broader than ours. Individual members
3 could meet our criteria, but the board itself didn't
4 until a certain date.

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

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

20 Practices change, training and experience
21 requirements change, and so forth. It seems unfair to
22 those individuals to penalize them on that basis when
23 they had met the prevailing training and experience
24 requirements at the time they were certified.

25 DR. HOWE: Dr. Zanzonico, this is Dr. Howe.

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

12 MS. BHALLA: Dr. Malmud, this is Neelam
13 Bhalla. May I speak?

14 CHAIRMAN MALMUD: Please do.

15 MS. BHALLA: Yes. So, for the purposes of
16 this rulemaking, the NRC Staff when we resolved this
17 petition, Ritenour's petition, we have -- we are
18 obligated to -- we are under, I suppose, as a condition
19 of that petition resolution, that we need to amend our
20 regulation in 35.57. And that relates to strictly people
21 who got boarded under the old Subpart J; so, therefore,
22 so far as the Ritenour petition goes and amending 35.57,
23 according to that, that's what we have done. And
24 anything beyond about this added issue about -- this
25 is beyond the scope of the Ritenour petition.

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1 MEMBER LANGHORST: Dr. Malmud, this is Sue
2 Langhorst.

3 CHAIRMAN MALMUD: Yes, Dr. Langhorst.

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

14 As the Part 35 rules have changed, Section
15 35.57 has gotten more and more complex. And let me tell
16 you, as an RSO it confuses me to no end, so I think
17 we all are in agreement that we would like to kind of
18 start with a clean slate so that board certified
19 individuals have an opportunity to practice their
20 profession, and I -- from a personal point of view,
21 I hope that NRC takes this opportunity to try to simplify
22 35.57 as much as possible, because it's just near
23 impossible to understand. So, thank you very much.

24 CHAIRMAN MALMUD: Thank you. This issue has
25 come up repetitively, and I think we all understand

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1 why the interpretation was given to it by the NRC, but
2 I think the vast majority of us don't agree with it.
3 Is that a fair statement?

4 (Chorus of yeses.)

5 CHAIRMAN MALMUD: So, we are asking the NRC
6 to recognize that we do not feel that the solution that
7 was arrived at, though logical, is practical, and we
8 are concerned that it will interfere with the practice
9 of the specialties involved. And, therefore, we would
10 encourage the NRC to attempt to resolve this for us
11 in some regulatory fashion that would not exclude people
12 from practicing who we feel by virtue of their training
13 are qualified despite the fact that their boards may
14 not have responded to the NRC's repeated requests to
15 meet those standards at that time; that this is a
16 deficiency in documentation rather than a deficiency
17 that's been demonstrated to be in practice. It's a
18 deficiency in documentation, and perhaps some exception
19 can be worked out so this can be resolved, because we're
20 concerned about the availability of these people to
21 practice their specialties on behalf of patient care.

22 MEMBER ZANZONICO: Dr. Malmud, this is Pat
23 Zanzonico. I would just like to append your statement
24 with the fact that we concede this is a separate but
25 perhaps related issue from the Ritenour petition and

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1 is outside the scope of the NRC's response to that
2 petition, but we think it warrants some remediation,
3 nonetheless.

4 CHAIRMAN MALMUD: Thank you, and that's
5 what we're requesting of the NRC Staff and its legal
6 consultants. We're seeking a practical solution to a
7 practical problem that will affect some practitioners
8 in a way which we feel is not in the best interest of
9 the end product which is patient care. May we move on,
10 because we're not going to resolve that particular
11 element of this discussion this conference call.

12 MEMBER ZANZONICO: Understood. I guess my
13 question is, and this is really for members of the ACMUI,
14 should we -- do we feel we want to vote and include
15 -- vote on and include this recommendation in our report
16 or not in light of the NRC staff's explanations and
17 clarifications?

18 CHAIRMAN MALMUD: Well, I think that the
19 --from the voices that I heard on the phone, the vast
20 majority agrees with your position, Dr. Zanzonico.

21 MEMBER ZANZONICO: Okay.

22 CHAIRMAN MALMUD: And I think that the -- we
23 recognize the nature of why the decision
24 -- recommendation was made by the NRC. They are driven
25 by the law, and the law must be adhered to. At the same

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1 time, it's an impractical solution given the fact that
2 there's a cutoff date which had to do with the law,
3 but would interfere with individuals who are competent
4 to do what they had been doing, but whose boards for
5 a variety of reasons which are difficult to understand,
6 did not meet the NRC request for documentation at that
7 time. So, all we can say is that we favor a generous
8 solution to the existing problem. It's not a larger
9 problem as 11 million undocumented aliens and,
10 therefore, we feel that solution might be able to be
11 worked out given some effort, additional effort by the
12 NRC staff and legal department in working with perhaps
13 even the Commissioners themselves to resolve a very
14 practical issue which doesn't affect an enormous number
15 of people, but could cause some individuals some
16 embarrassment. And, therefore, you can put your motion
17 forward, Dr. Zanzonico.

18 MEMBER ZANZONICO: Okay. Then I'll make the
19 motion that we adopt the following recommendation; that
20 is, that the date of recognition of a recognized -- the
21 date of recognition of a certifying board should not
22 impact individuals being named as authorized
23 professionals, AUs, Authorized RSOs, et cetera, so that
24 is the motion.

25 CHAIRMAN MALMUD: That is the motion. Is

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1 there a second to that motion? I don't hear a second.

2 VICE CHAIR THOMADSEN: This is Bruce
3 Thomadsen.

4 CHAIRMAN MALMUD: Dr. Thomadsen. You
5 seconded it?

6 VICE CHAIR THOMADSEN: Yes.

7 CHAIRMAN MALMUD: Thank you. Is there
8 further discussion?

9 (No response.)

10 CHAIRMAN MALMUD: We recognize that we are
11 making a recommendation as a consulting body, and that
12 it may -- a portion of it may be not approved, but we
13 want the spirit of the recommendation to be clearly
14 transmitted to the interested parties in the best
15 interest of maintaining the ability of individuals to
16 practice on behalf of the public. So, all in favor of
17 the motion?

18 (Chorus of ayes.)

19 CHAIRMAN MALMUD: Any opposed? I hear no
20 opposition. Any abstentions?

21 (No response.)

22 CHAIRMAN MALMUD: So, the motion is passed
23 unanimously which should assist in addressing the
24 importance of the issue including that element of it
25 to the bodies that we consult for within the NRC.

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1 Dr. Zanzonico, any other items?

2 MEMBER ZANZONICO: Yes, there are. So, we
3 want to move on to Item 4 in our report, and this has
4 to do with the measuring moly breakthrough, and
5 reporting of failed breakthrough tests. And to expedite
6 matters on this point, there -- I think we are all in
7 agreement, we on the ACMUI are all in agreement with
8 the provisions of the proposed rule requiring testing
9 of moly breakthrough on every elution of a moly-tech
10 generator rather than after only the first elution.

11 There are two contentious issues, though,
12 which have arisen in the course of our last
13 teleconference and subsequent emails. The first of
14 these is related to the reporting of out-of-tolerance
15 breakthrough results.

16 The proposed NRC rule, as I understand it,
17 is requiring a reporting to the -- by the user, by the
18 licensee requiring reporting of out-of-tolerance
19 elution results, breakthrough results to the NRC, and
20 to the manufacturer.

21 The two options are reporting the results
22 only to the manufacturer and leaving it to the
23 manufacturer to report these results to the NRC. And
24 the second option would be to recommend the proposed
25 NRC rule requiring dual reporting. That's the first

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1 issue.

2 The second issue is related to generators
3 not included in the covered proposed rule, and there
4 was concern among the ACMUI members that -- about
5 generators that might be introduced in the near future
6 like germanium/gallium generators and what to do with
7 those in terms of breakthrough testing. And one
8 possibility would be to the -- for the NRC to generalize
9 its rule to address future generator systems, and the
10 alternative would be that the NRC by regulation adopt
11 the FDA label instructions, the package insert for
12 generator QC procedures. And the rationale for that
13 latter approach would be that it would not require
14 revision of NRC rules as each new generator system is
15 introduced.

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

23 MEMBER VAN DECKER: Dr. Malmud.

24 CHAIRMAN MALMUD: Yes, thank you.

25 MEMBER VAN DECKER: This is Bill Van Decker.

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1 Can I speak to that first?

2 CHAIRMAN MALMUD: Yes, Dr. Van Decker.

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

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

24 I don't think we all disagree with the
25 concept of everyone in the current era with current

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

12 CHAIRMAN MALMUD: Dr. Van Decker is seeking
13 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 any
18 experience with rubidium generator but certainly have
19 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 molybdenum
23 breakthrough in any of the generators that we use at
24 the various locations that I've been over the course
25 of my career. So, while the reporting may be a bit

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

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

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

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

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

24 It took a while for the investigation to
25 follow but there was a manufacturing issue underlying

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

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

24 CHAIRMAN MALMUD: Thank you, Dr. Suleiman.
25 We've heard from two members of the Committee both of

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1 whom are supportive of the dual reporting line, both
2 the manufacturer and the NRC. Are there any voices in
3 support of that, as well, or who oppose that?

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

6 CHAIRMAN MALMUD: Yes, Steve.

7 MEMBER MATTMULLER: And I do have a few
8 comments in regards to this. I believe the justification
9 for the proposed reporting requirements have
10 misidentified past incidents as radiation safety
11 incidents but, in fact, they are a product quality
12 issue.

13 The breakthrough test in question is a
14 radiopharmaceutical product quality control test. The
15 testing procedure is clear. The licensee is to perform
16 the measurement for breakthrough before the product
17 is used. If the product passes the measurement, then
18 it may be used for patients. If the product fails the
19 measurement then it may not be used for patients.

20 The discussion within the proposed rule
21 misses this fact, I think, from past incidents; that
22 is, when pharmacists found breakthrough limits that
23 were exceeded in their technetium-99m elutions, they
24 discarded the elution, patients were not injected. If
25 a product fails this measurement it's a product quality

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1 issue that is best solved by the licensee contacting
2 the manufacturer.

3 If a licensee has a generator that fails
4 breakthrough testing they are, in essence, out of
5 business. If they want to return to business, they have
6 to call the manufacturer because only the manufacturer
7 can supply a replacement generator for the defective
8 generator. And believe me, this is a strong incentive
9 for a licensee to contact a manufacturer.

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

15 An important component of these computer
16 systems is the calculations that are automatically
17 performed for moly-99 breakthrough testing. As one
18 assays the technetium-99m and the moly content of an
19 elution, this information is entered into the program
20 and it automatically calculates the ratio of technetium
21 to moly.

22 If it passes, it's good to go. If it doesn't
23 pass, it can't be used for making -- for kits or for
24 being used to dispense for doses. In fact, some
25 pharmacies now are even going one step further and

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1 they're printing the moly-99 content on the individual
2 technetium-99m unit dose labels.

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

11 In other words, if a licensee is following
12 the regulations and performing a breakthrough test,
13 the NRC will only see reports regarding product
14 qualities or issue regarding product quality.

15 So, I would say the NRC responsibility is
16 patient safety. The best way to insure patient safety
17 is that a safe product is being used. The best response
18 from the NRC should be to do the breakthrough testing
19 according to FDA product labeling.

20 I'd also like to make a few additional
21 comments on the rationale listed in the proposed
22 regulations as justifications for the new reporting
23 requirements. One of the first --

24 CHAIRMAN MALMUD: Steve?

25 MEMBER MATTMULLER: Yes?

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

4 MEMBER MATTMULLER: Yes, I am.

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

7 MEMBER MATTMULLER: Not a problem. The
8 first justification was that the FDA may not investigate
9 each reported incident and may take a considerable
10 amount of time in investigating the cause of reported
11 failures. This is probably an accurate description of
12 past FDA actions, but without knowing the specifics
13 of each event, this is probably an entire appropriate
14 action by the FDA.

15 According to FDA current good
16 manufacturing practices, if a manufacturer gets a
17 product complaint, there are several standard operating
18 procedures in place that they must follow. One of these
19 standard operating procedures is that the manufacturer
20 will start an investigation as to the cause of the
21 problem, and the result of the investigation and any
22 proposed modifications to the manufacturing process,
23 and any validation studies of these modifications will
24 all be available for FDA review.

25 Even though the FDA may not have its

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1 inspectors in the manufacturer's facility at the time,
2 in a very big way an inspection is being conducted in
3 a manner approved by the FDA. Think of these standard
4 operating procedures as representative of its in-house
5 FDA office within the manufacturing site in that these
6 SOPs, or standard operating procedures are all FDA
7 approved and they direct the actions of the manufacturer
8 in these and all other situations.

9 I'll skip to the third and come back to
10 the second. The third statement was, additionally, some
11 incidents of failed generators may not be reported to
12 the FDA because certain manufacturers are not in the
13 United States. And the generators are distributed by
14 vendors who are not required to report to the FDA.

15 Whether or not a company's headquarters
16 or its manufacturing site is inside or outside of the
17 United States is misleading. If a product is used in
18 the United States, it will have FDA approval. Its
19 application for this drug, its standard operating
20 procedures, its manufacturing site will all be
21 reviewed, inspected, and approved by the FDA before
22 the product comes to market.

23 If a licensee's generator is not
24 performing well and that licensee can't use it for their
25 patients, they will contact the manufacturer, as only

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1 the manufacturer can send them a replacement generator.

2 There was also a statement about how the
3 generators are distributed by vendors who are not
4 required to report to the FDA. I'm not clear to the
5 intent of this because to my knowledge the vast majority
6 of generators are sold direct to the licensee by the
7 manufacturer; 95 percent of all technetium generators
8 are sold direct to commercial nuclear pharmacies. The
9 other 5 percent are sold direct to large medical
10 institutions such as Massachusetts General or
11 Sloan-Kettering. All the rubidium-82 generators are
12 sold direct by Bracco.

13 If there is a unique example of a vendor
14 distributing a generator that would represent a very
15 small percentage of all generators, it would be doubtful
16 this small number could justify a regulatory action.
17 Plus, in a sense it doesn't matter. A failed generator
18 is a failed generator. Even if a vendor is involved,
19 the licensee is out of business. If a vendor is contacted
20 by the licensee that they have a failed generator, the
21 vendor has to contact the manufacturer to arrange for
22 a replacement generator for the licensee.

23 In regards to the second statement, the
24 NRC believes that requiring each incident of a failed
25 generator to be reported would provide the NRC the

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1 opportunity to evaluate and take prompt action, as
2 needed.

3 Again, these are not radiation safety
4 issues; these are drug quality issues, clearly in the
5 realm and expertise of the FDA. The generator's
6 manufacturer radioactive materials license is for the
7 safe use of radioactive material within their
8 manufacturing facility. This license is concerned with
9 items such as radiation exposure to the employees,
10 proper security of the radioactive material, and proper
11 disposal of radioactive waste. These are all areas of
12 the NRC's expertise and regulatory charge.

13 A manufacturer's radioactive material
14 license, though, from the NRC should not be used as
15 a pathway to investigate a manufacturer's manufacturing
16 procedures. These procedures are clearly the expertise
17 of the FDA.

18 To allow the NRC a pathway to investigate
19 manufacturer's procedures would be akin to allowing
20 the FDA to investigate operating procedures at a nuclear
21 power plant. It would be inappropriate.

22 But even if these reports are allowed, any
23 subsequent investigation by the NRC will have a very
24 unequal effect on the various generator manufacturers.
25 One has to remember that the NRC's regulations are

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1 enforced by 37 Agreement States in the U.S. And just
2 as the NRC really does not have the appropriate staff,
3 such as a chemical engineer or a radiochemist with FDA
4 manufacturing experience, neither do the respective
5 Agreement State Radiation Protection Programs.

6 As a reminder, the Covidien manufacturing
7 sites in St. Louis, Missouri, the Lantheus
8 manufacturing sites in Boston, Massachusetts, and one
9 of the manufacturing sites for the Bracco rubidium
10 generator is in Ottawa, Canada.

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

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

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1 rubidium-82 generator incident, the NRC only had an
2 advisory role as the manufacturing site was in New
3 Jersey.

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

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

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

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

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

5 (No response.)

6 CHAIRMAN MALMUD: Pat.

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

9 CHAIRMAN MALMUD: Please do.

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

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

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

7 CHAIRMAN MALMUD: But, Dr. Zanzonico, your
8 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 that
15 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 that
20 the breakthrough be reported to the NRC.

21 MEMBER LANGHORST: Dr. Malmud, this is Sue
22 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. This
3 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 NRC.
8 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 vote
14 then, and we'll have to do this by each individual
15 identifying himself or herself. So, those in favor of
16 the motion are, number one, Dr. Zanzonico.

17 MEMBER ZANZONICO: In favor, yes.

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

20 MEMBER WEIL: Laura Weil.

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

23 MEMBER PALESTRO: Chris Palestro.

24 CHAIRMAN MALMUD: Dr. Palestro. Number
25 four?

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1 MEMBER SULEIMAN: Orhan Suleiman.

2 CHAIRMAN MALMUD: Dr. Suleiman. Number
3 five?

4 VICE CHAIR THOMADSEN: Bruce Thomadsen.

5 CHAIRMAN MALMUD: Dr. Thomadsen. Six? Is
6 there a sixth?

7 (No response.)

8 CHAIRMAN MALMUD: I do not hear a sixth.
9 Those opposed to the motion? Number one? Steve?

10 MEMBER MATTMULLER: Steve, yes.

11 CHAIRMAN MALMUD: Number two?

12 MEMBER LANGHORST: This is Sue Langhorst.
13 I'm opposed.

14 CHAIRMAN MALMUD: Dr. Langhorst. Number
15 three?

16 MEMBER BAILEY: Darice Bailey.

17 CHAIRMAN MALMUD: Thank you. Number four?

18 MEMBER VAN DECKER: Van Decker.

19 CHAIRMAN MALMUD: Dr. Van Decker. Number
20 five?

21 MEMBER WELSH: Jim Welsh.

22 CHAIRMAN MALMUD: Dr. Welsh. Six?

23 MEMBER SUH: John Suh.

24 CHAIRMAN MALMUD: Dr. Suh. Seven?

25 MEMBER GUIBERTEAU: Mickey Guiberteau.

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1 CHAIRMAN MALMUD: Dr. Guiberteau. Eight?
2 So, the motion fails by a vote of 7-5. The Chair has
3 not voted. Thank you.

4 Now, Dr. Zanzonico, you have another
5 motion, do you not?

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

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

24 CHAIRMAN MALMUD: Thank you, Dr. Zanzonico.
25 Are there comments?

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1 MEMBER BAILEY: Yes, this is Darice Bailey.

2 CHAIRMAN MALMUD: Yes.

3 MEMBER BAILEY: I would like to clarify from
4 a regulatory standpoint whether you're saying that NRC
5 should, or the Agreement States, whatever, should adopt
6 FDA's label or if through rule or license conditions
7 require the licensee -- that the licensee follows the
8 package insert, which is different things.

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

13 MEMBER BAILEY: I would, too.

14 MEMBER ZANZONICO: Yes.

15 CHAIRMAN MALMUD: Thank you for clarifying
16 that. Other comments?

17 MEMBER SULEIMAN: Dr. Malmud, this is Orhan
18 Suleiman.

19 CHAIRMAN MALMUD: Dr. Suleiman.

20 MEMBER SULEIMAN: I want to clarify that
21 it's not accepting an FDA approved label. This is the
22 manufacturer's operating instructions. This whole
23 thing is put together by the manufacturer, though we
24 eventually approve it, so it's not like our version
25 versus theirs. And a point of distinction, though I

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1 don't know different people interpret it differently,
2 I think what we were focusing on was the breakthrough
3 limit as specified in the label. Obviously, how they
4 do breakthrough is important and should be following
5 the manufacturer's instructions.

6 A third point is that recently, for
7 example, the strontium-rubidium generator, the
8 manufacturer decided to lower the breakthrough limit,
9 so the NRC through rulemaking has etched in the
10 regulations a limit that the company has now changed.
11 So, this would give the NRC a little bit more flexibility
12 in that they could say, you know, the limit is what
13 the label specifies, so if you get a new generator where
14 maybe the impurities are even less, they want to change
15 the limit, you get a different type of generator, you
16 have a completely different, you know, specified amount
17 of radionuclide per breakthrough. That would all be
18 taken care of very easily, and that way it would also
19 allow for making changes in manufacturing.

20 CHAIRMAN MALMUD: Thank you, Dr. Suleiman.
21 So, you're speaking in favor of the NRC asking that
22 the manufacturer's label, which is eventually approved
23 by the FDA, be the guideline.

24 MEMBER SULEIMAN: Be the regulation.

25 CHAIRMAN MALMUD: Be the regulation. Did

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1 I interpret that correctly?

2 MEMBER SULEIMAN: And, in fact, they've
3 always done that with the label, but then manufacturers
4 may change the requirement, and the NRC is stuck holding
5 a regulation that's outdated that then has to go through
6 rulemaking to change.

7 CHAIRMAN MALMUD: When the manufacturer
8 changes the label doesn't that require FDA approval?

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

12 CHAIRMAN MALMUD: Yes.

13 MEMBER SULEIMAN: And they say we want to
14 make these changes. You know, we've learned some new
15 things, we want to -- for a multitude of reasons. And
16 when the new label comes out it basically replaces the
17 old label.

18 CHAIRMAN MALMUD: Yes, I understand. So,
19 that really simplifies it for the end user by having
20 one standard to adhere to.

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

22 CHAIRMAN MALMUD: Thank you.

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

25 CHAIRMAN MALMUD: Of course, Dr.

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1 Guiberteau.

2 MEMBER GUIBERTEAU: This is sort of a
3 curious circumstance, but in terms of the FDA labeling
4 and requirements for a generator, as well as putting
5 some limits on the -- approving the limits of the
6 manufacturer on the moly breakthrough, let's say in
7 the instance of a molybdenum-99, technetium-99
8 generator. If -- what are the implications for
9 off-label use in the sense of medical necessity if there
10 is not an absolute limit within say the NRC regulations?

11 And just by way of example, if I were to
12 elute a generator and I had exceeded the 0.15
13 microcuries per millicurie, but felt that I had an
14 emergency procedure that needed to be performed, and
15 I used this anyway. Would that be something that would
16 be defensible?

17 MEMBER SULEIMAN: I think that would -- Dr.
18 Malmud, Orhan Suleiman again. I think that's a perfect
19 example of justified practice of medicine issue. You
20 know, you may have an emergency. This may be the only
21 generator available, this may be the only test that
22 would give you relevant efficacious information, and
23 you exercise your authority as a practitioner of
24 medicine. And I would not see any problem with that
25 at all. Our oncologists, I talk to them all the time,

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1 and I said so you can change your dose? I said, you
2 know, in terms of chemo or whatever or change the
3 protocols, he says oh, yes, that's -- we can do that
4 under our practice of medicine. So, even though we have
5 an official protocol that's approved as part of the
6 label, physicians -- and I'm going to defer to the other
7 physicians on the panel, oncologists, my understanding
8 is that's done often, you know, if you feel that
9 something may improve for a specific patient. So, the
10 answer to your question is it would be justified.

11 MEMBER GUIBERTEAU: And do you see that as
12 a difference in culture between say such a regulation
13 of an absolute limit in the NRC as opposed to one made
14 by the manufacturer under FDA labeling?

15 MEMBER SULEIMAN: What the -- this is - I,
16 you mean, we sometimes to get policy have to go through
17 all sorts of reviews and whatever. This is clearly my
18 interpretation of our policy, but if I think somebody
19 is circumventing the regulations and saying I'm doing
20 this under practice of medicine, but clearly doesn't
21 want to comply with the safety aspects of it, at that
22 point I believe they assume -- they do assume the
23 liability themselves. And as long as everything works
24 out okay, it's acceptable.

25 Most of the manufacturers when they

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1 develop a medical product they're working hand and hand
2 with the user community, with the physicians. So, it's
3 not a them or us thing. I think everybody is trying
4 to get a product out that's going to be safe, that's
5 easy to use, and there are some safety standards in
6 place. So, your example was pretty easy, you know, but
7 sometimes when people really border on negligence, you
8 know, do they want to invoke -- often they'll blame
9 some other person or some -- you know, they were
10 confused with the instructions, or they'll blame one
11 of the intermediary health professionals. But I don't
12 think -- I don't see where somebody would go against
13 what the manufacturer is recommending.

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

16 MEMBER SULEIMAN: Did I confuse or --

17 CHAIRMAN MALMUD: No, I think you clarified
18 it, at least you clarified it for me, Dr. Suleiman.

19 MEMBER SULEIMAN: Thank you.

20 MEMBER GUIBERTEAU: And me, also.

21 CHAIRMAN MALMUD: Other comments?

22 MEMBER VAN DECKER: Dr. Malmud, this is Bill
23 Van Decker.

24 CHAIRMAN MALMUD: Yes, Dr. Van Decker.

25 MEMBER VAN DECKER: I think I would echo

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1 some of the comments of some of the people that have
2 spoken prior. I think that we all want to look at
3 generators as a non-generic set of issues here because
4 there may be more down the line, and we want them all
5 handled in a similar level playing field kind of
6 situation. So, I think that that's a good idea.

7 I think the concept of not having very,
8 very specific numbers in rulemaking space is also a
9 wonderful concept because we know, and we're watching
10 even now how long it takes rulemaking to get readjusted.
11 So, I think we want to make sure we give ourselves the
12 leeway as the science evolves and as we see how things
13 play out.

14 I have to admit that I'm hopeful that the
15 FDA labeling concept works, or possibly not knowing
16 the fine points of the legality of some of this it makes
17 me a little nervous because, you know, physicians always
18 talking about on-label and off-label, and how quickly
19 does that change, and what's the update. You know, I
20 think I had spoken to a few people about the possibility
21 of, you know, can we do some of this in appendix space
22 rather than just use FDA label or just change numbers,
23 or use -- or make it somewhat clear that the FDA's
24 labeling concept here applies only to the breakthrough
25 component of the eluate per se. So, I don't know the

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1 real answers to that, but if people who know more than
2 me believe that this fulfills the reality of being
3 flexible, allowing for us to move the science forward,
4 and to make changes we need to, then I trust people
5 in that regard.

6 CHAIRMAN MALMUD: Thank you, Dr. Van
7 Decker.

8 DR. HOWE: Dr. Malmud, this is Dr. Howe.
9 May I speak?

10 CHAIRMAN MALMUD: Yes, Dr. Howe.

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

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1 the licensee from comply with the applicable FDA, other
2 federal and state requirements governing radioactive
3 drugs or devices.

4 But we did not say, and in 2002 they tried
5 to go to plain language and say you're required to follow
6 the FDA requirements. And we very carefully went back
7 and said no, we cannot do that. We just can only say
8 that you're not relieved of following them. So, to try
9 to in rulemaking put NRC following an FDA package insert
10 and enforcing an FDA package insert would be taking
11 us back to pre-1994 situations in which the medical
12 and the pharmacy community said we were doing the wrong
13 thing. Thank you.

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

16 CHAIRMAN MALMUD: Yes, Steve.

17 MEMBER MATTMULLER: Part of the issues that
18 were raised back then were that -- were, for example,
19 indications of when what specific test a
20 radiopharmaceutical could be used for. And if it wasn't
21 in the package insert, then a licensee was in
22 non-compliance if they used it for a different
23 indication; and/or in regards to preparing a kit
24 according to the manufacturer's instructions, Orhan
25 touched on it, to sometimes change product information

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1 is a costly experience for the manufacturer, so even
2 though they know the field is say, for example, putting
3 400 millicuries of technetium into a sulfur colloid
4 kit versus the product label of 200, they know people
5 are doing quality control testing and it's a safe
6 product, but they're not going to go through the time
7 and expense to revise the product labeling to say yes,
8 you can now add 400 millicuries of pertechnetate to
9 a sulfur colloid kit.

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

22 And I'd also like to make a -- it's been
23 touched on. This is a current problem now with rubidium
24 generator in that there are more restrictive testing
25 requirements in the product labeling, but NRC

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1 regulations aren't even addressing it in this revision.
2 And it could be another seven to ten years before they
3 do accept it with the current strategy that the NRC
4 uses for this type of enforcement.

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

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

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

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

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

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

5 CHAIRMAN MALMUD: Thank you. Dr. Zanzonico?

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

15 MEMBER SULEIMAN: This is Orhan Suleiman
16 again.

17 CHAIRMAN MALMUD: Yes, Dr. Suleiman.

18 MEMBER SULEIMAN: Okay. A point of
19 clarification, the way I interpret it. We were basically
20 referring to the breakthrough limit in the label. I
21 don't think we were implying that the NRC adopt the
22 entire label, which then could be subject to all sorts
23 of different interpretations. I think here we're
24 talking about the quantitative limit as specified in
25 the label.

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

3 MEMBER ZANZONICO: It is now. I think that's
4 an important clarification, and I think our
5 recommendation should reflect that point.

6 CHAIRMAN MALMUD: That would be a
7 limitation to the breakthrough level in the label. Who
8 seconded your motion, Dr. Zanzonico?

9 MEMBER ZANZONICO: Well, I don't think I
10 actually made the formal motion, but I'll be happy to
11 do so.

12 CHAIRMAN MALMUD: All right.

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

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

20 MEMBER MATTMULLER: I'll second it. Steve
21 Mattmuller.

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

24 DR. HOWE: I --

25 CHAIRMAN MALMUD: You don't want to -- I'm

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1 sorry, I didn't hear you.

2 DR. HOWE: Oh, Neelam will speak.

3 CHAIRMAN MALMUD: Thank you.

4 MS. BHALLA: Yes, this is Neelam Bhalla.

5 And we believe this for -- as a rule writer we have
6 been always guided that in our rules we should state
7 the limits, what the regulations are directly in our
8 regs so that a licensee is not referred to or not sent
9 somewhere else. And this is referred to as incorporation
10 by reference.

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

17 So, in this particular case I'm not really
18 sure if we are treading onto that wrinkle where we are
19 sending the licensee somewhere else. So, I'll be a
20 little bit reluctant on -- and I just wanted you to
21 know about that, that we -- generally, we like to put
22 whatever the regs are, whatever numbers are right in
23 our regs.

24 CHAIRMAN MALMUD: Thank you for that
25 clarification. I wanted to -- the purpose of my asking

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1 for it was to have it expressed so that the Committee
2 members will understand the issue. I heard another
3 voice?

4 VICE CHAIR THOMADSEN: That is Bruce
5 Thomadsen. May I comment?

6 CHAIRMAN MALMUD: Please, Dr. Thomadsen.

7 VICE CHAIR THOMADSEN: I very much
8 appreciate the NRC trying to keep everything in the
9 one document, and I think as a user it is very convenient
10 to do so. The problem that's trying to be addressed
11 here is the ossification of the recommendations even
12 as situations change, and the recommendations get out
13 of date and actually may become dangerous.

14 The question of sending the user somewhere
15 else and having them look these things up is not as
16 big of a problem here as it would be if you were referring
17 to an ICRP report to which many people may not have
18 ready access. But if you're dealing with a generator,
19 it's assumed that you also do have their package insert,
20 and you would have the recommendations that go with
21 the package insert right there before you.

22 MEMBER BAILEY: Dr. Malmud, this is Darice
23 Bailey. May I speak?

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

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1 MEMBER BAILEY: I want to add to his point,
2 NRC in their transportation rules referenced Title 49
3 extensively and it's really difficult to look them up.
4 So, it is done in NRC rule territory to reference other
5 numbers.

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

16 I, personally, do not know what they are
17 off the top of my head, but I just want to warn you,
18 you know, opinion doesn't matter here. This is something
19 that may be dictated by what the legal standards are.
20 I just want to caution you on that. You can make a
21 recommendation that I can go back and research this
22 out, or discuss this with my management and find out
23 that this is not legally permissible.

24 CHAIRMAN MALMUD: Thanks.

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

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1 CHAIRMAN MALMUD: Thank you, Counselor
2 Chidakel. That's why I raised the issue the way that
3 I did, because I wanted the Committee members to
4 understand that our recommendation might not be
5 accepted. We don't --

6 MEMBER VAN DECKER: Dr. Malmud.

7 CHAIRMAN MALMUD: I'm sorry, who's
8 speaking?

9 MEMBER VAN DECKER: This is Bill Van Decker.

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

15 MEMBER VAN DECKER: Yes. I think that, you
16 know, we're not going to solve the exact wording here
17 today. But I think that, you know, the thing that has
18 come across everyone who has spoken is that we're
19 looking for something not written in stone in rulemaking
20 space that doesn't allow us dexterity to change with
21 the times; that if we go with something along the concept
22 of FDA labeling, we're really talking about only the
23 breakthrough piece and not the rest of the clinical
24 piece of this. And, you know, whether that is some other
25 way to describe what we're trying to refer to, or whether

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1 that's some way to create some appendix with exact
2 numbers that fulfill the spirit of what's FDA labeling
3 in that regard, I think that most of us would probably
4 be flexible with that, but we would kind of prefer to
5 see, you know, some good be done for long-term stuff.
6 And, I guess, the real proof of the pudding will be
7 when we all see the exact wording that tries to get
8 us to where we're all trying to go.

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

12 MEMBER SULEIMAN: Dr. Malmud.

13 CHAIRMAN MALMUD: Yes, Dr. Suleiman.

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

19 These are very product-specific so you're
20 not going to be hunting for a different -- you should
21 have your user manual, or your label, or your
22 instructions right there. It's no different than saying
23 you should tune up your car, but then you decide, and
24 you say all the parts have to be tested, have to be
25 3,000 rpm at this setting. Well, it's going to vary

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1 by car, so in this case each generator, you know, has
2 the manufacturer's specified limit, so I think it's
3 quite prescriptive. And that way you're not stuck with
4 using a limit that may have changed.

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

7 MEMBER MATTMULLER: I'm sorry, could I make
8 one more comment?

9 CHAIRMAN MALMUD: Yes. Who's --

10 MEMBER MATTMULLER: I'm sorry, Steve
11 Mattmuller.

12 CHAIRMAN MALMUD: Thank you, Steve.

13 MEMBER MATTMULLER: One other advantage
14 this strategy would have is that for a long time the
15 vast majority of moly-99 used in the U.S. came from
16 two reactors, and their HEU uranium came from one
17 supplier, the U.S. Government. We're now in a transition
18 phase moving to low-enriched uranium coming from
19 different -- a far greater web of reactors all using
20 LEU, all using our own target design, and these new
21 target designs all have new target processing
22 procedures.

23 And in addition to reactors producing
24 moly, we have new linear accelerator manufacturers
25 trying to come on line, so there could be a whole new

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1 wrinkle to rating the quota of contamination in our
2 generators. And this will be identified and handled
3 by the FDA, but it's going to be -- and then any
4 subsequent would be in their package insert, which by
5 the way does come with each generator when you receive
6 it.

7 So, the way I look at this, if the NRC is
8 saying patient safety, radiation safety, I think it's
9 incumbent upon them to find a way to do it this way,
10 because to me it's unconscionable to think that if a
11 new generator gets approved, it could take seven to
12 ten years in the typical process for it to ever make
13 it into an NRC reg. Thank you.

14 CHAIRMAN MALMUD: Thank you.

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

16 CHAIRMAN MALMUD: Yes, Dr. Howe.

17 DR. HOWE: There's another process, that
18 if we get a new generator that is significantly
19 different from what we have seen in the past; in other
20 words, the moly breakthrough has to have different
21 values, we can move things into 35.1000 and handle those
22 in a matter of a few months, so one should not think
23 that we need to get everything into rulemaking in order
24 to handle new products. And that's what the purpose
25 of 35.1000 is. Thank you.

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

4 (Chorus of ayes.)

5 CHAIRMAN MALMUD: Any opposed? Any
6 abstentions?

7 (No response.)

8 CHAIRMAN MALMUD: The motion carries
9 unanimously. Thank you. Next item, Dr. Zanzonico.

10 MEMBER ZANZONICO: Okay. I think some of
11 the remaining items will move quickly, at least I hope
12 that's the case.

13 So, this moves us on to item 5, allowing
14 Associate Radiation Safety Officers, ARSOs, to be named
15 on a medical license. And the draft recommendation in
16 our report is that the ACMUI recommends that addition
17 of ARSOs and temporary RSOs be included in exemptions
18 in the same manner as AUs, ANPs, Authorized Nuclear
19 Pharmacists, and Authorized Medical Physicists. So,
20 the crux of this recommendation is to endorse the
21 inclusion of ARSOs being named on medical licenses.

22 CHAIRMAN MALMUD: That's a motion. Is there
23 a second to the motion?

24 MEMBER LANGHORST: This is Sue Langhorst.
25 I'll second that.

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1 CHAIRMAN MALMUD: Thank you. Is there
2 discussion of the motion?

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

5 CHAIRMAN MALMUD: Please do.

6 MEMBER LANGHORST: As you can see in the
7 draft report, these are exemptions for the Type A Broad
8 Scope licensees, and the crux of the request is that
9 just like Authorized Users, Authorized Medical
10 Physicists, Authorized Nuclear Pharmacists are named
11 by the Radiation Safety Committee of those Type A Broad
12 Scope licensees, we'd like to be able to have that same
13 flexibility for ARSOs and clarify it for temporary RSOs,
14 also. Thank you.

15 CHAIRMAN MALMUD: Thank you. Further
16 discussion?

17 (No response.)

18 CHAIRMAN MALMUD: All in favor of the
19 motion?

20 (Chorus of ayes.)

21 CHAIRMAN MALMUD: Any opposed? Any
22 abstentions?

23 (No response.)

24 CHAIRMAN MALMUD: The motion carries
25 unanimously. Dr. Zanzonico, you're on a run. You want

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1 to take --

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

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

21 CHAIRMAN MALMUD: I'm certain that no one
22 objects.

23 MS. BHALLA: Dr. Malmud.

24 CHAIRMAN MALMUD: Neelam.

25 MS. BHALLA: Yes, this is Neelam. I just

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1 wanted to say I wholeheartedly agree that it becomes
2 a very long document, and it sounds and looks very
3 repetitious. But this is a Federal Register Notice of
4 the proposed regulations. We are bound by our procedures
5 whereby we need to follow section by section what we
6 are changing and why we are changing. So, although 100,
7 200, 300 and so on, they are pretty much similar, but
8 because of these stipulations we need to follow that
9 process.

10 And, also, about the -- it's very well
11 said, but the -- you know, we could do bullet form,
12 but again we are bound by our own writing style. And,
13 therefore, we hear you but that's a way we are supposed
14 to do it.

15 CHAIRMAN MALMUD: Thank you, Neelam. We
16 understand that, and that's why I suspect Dr. Zanzonico
17 made a recommendation for those of you who actually
18 draft these to do what you do best. Dr. Zanzonico.

19 MEMBER ZANZONICO: Okay. Well, we're really
20 down the home stretch. There was a seventh item, that
21 was just additional general comments. And really the
22 most notable of these, in effect, has been eliminated,
23 and that had to do with the separate training and
24 experience requirements for beta gamma versus alpha
25 emitters. We really addressed that in our previous

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1 discussion and the previous item. And I thank Dr.
2 Langhorst for correctly pointing out that Item 7B really
3 is no longer necessary based on our earlier actions,
4 so that's been eliminated.

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

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

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

24 So, again I don't think, unless anyone on
25 the Committee feels otherwise, that they warrant

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1 additional discussion. Basically, these Significant
2 Comments are made to insure compatibility between what
3 we were recommending among our general items that we
4 discussed at length already and the related specific
5 passages in the proposed rule.

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

9 MEMBER ZANZONICO: Eight through eleven.

10 CHAIRMAN MALMUD: Yes.

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

14 CHAIRMAN MALMUD: Is there any discussion
15 of these?

16 (No response.)

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

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

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1 or a colon. And that's really the balance of the report.

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

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

7 CHAIRMAN MALMUD: Yes, Neelam.

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

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

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

19 I also would like to mention that we
20 decided we were going to only be giving you substantive
21 and major things at this point, and we realized when
22 we gave you this draft, and I realized when we gave
23 you this draft that we have a lot of changes that we're
24 still making to the actual language, so that it's not
25 just that we are bound by certain restrictions with

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1 regard to your minor comments, but some of those things
2 may go away just through editing and through fine comb
3 tothing, whatever.

4 MS. BHALLA: Yes.

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

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

19 Dr. Zanzonico, you have taken us right
20 through this document.

21 MEMBER ZANZONICO: Yes, we have.

22 CHAIRMAN MALMUD: And it looks like it's
23 a grand slam. And we still have a minute or two, but
24 I think we have to ask Chris who's the official
25 representative who opened the meeting if he has any

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1 comments at this point, or his delegate.

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

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

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

22 CHAIRMAN MALMUD: Thank you, Chris.

23 MS. HOLIDAY: I just wanted to add that at
24 this time, as Chris mentioned, we have to get the
25 finalized report from you, so you actually have to vote

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1 on finalizing the report pending these -- the
2 incorporation of these revisions and recommendations,
3 and since this is the only meeting time to do it, I
4 guess this would be the time now that the full Committee
5 would need to vote to approve the Subcommittee report
6 to include those revisions as mentioned during this
7 teleconference to finalize the report now.

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

10 MEMBER ZANZONICO: I guess that's me.

11 CHAIRMAN MALMUD: You're the Chairman of
12 the Subcommittee.

13 MEMBER ZANZONICO: Yes. So, I make a motion
14 that the Subcommittee approve our report pending
15 incorporation of all suggested or all approved
16 revisions.

17 CHAIRMAN MALMUD: Is there a second to the
18 motion?

19 MEMBER GUIBERTEAU: Mickey Guiberteau, I
20 second this.

21 CHAIRMAN MALMUD: Thank you, Dr.
22 Guiberteau. Any further discussion of this report with
23 all the recommendations made in these six hours of
24 conferences that we've had?

25 MEMBER LANGHORST: Dr. Malmud, this is Sue

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1 Langhorst.

2 CHAIRMAN MALMUD: Dr. Langhorst.

3 MEMBER LANGHORST: I'd just like to clarify
4 that that motion is for the full Committee and not just
5 the Subcommittee?

6 CHAIRMAN MALMUD: That's correct.

7 MEMBER LANGHORST: Yes, thank you.

8 CHAIRMAN MALMUD: The motion is coming from
9 the Chair of the Subcommittee to the entire Committee.
10 That is its purpose.

11 MEMBER LANGHORST: Thank you.

12 CHAIRMAN MALMUD: Thank you for clarifying
13 that for anyone who might not have understood that.
14 Appreciate it. So, all in favor?

15 (Chorus of ayes.)

16 CHAIRMAN MALMUD: Are there any opposed?
17 We hear no opposed. Are there any abstentions?

18 (No response.)

19 CHAIRMAN MALMUD: We hear none, so the
20 Committee passes this unanimously, that's the ACMUI
21 passes this recommendation of the Subcommittee
22 unanimously, and we thank the Subcommittee and each
23 of its members for an enormous amount of effort. We
24 spent six hours in discussing this but that's a fraction
25 of what the members of that Committee spent on drafting

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1 and crafting this document, so we're very appreciative
2 of it.

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

5 MR. EINBERG: Nothing from this end. I
6 believe that when you're ready to adjourn, you can
7 adjourn.

8 MEMBER ZANZONICO: Can I just ask one point
9 of clarification. At this point what is our submission
10 deadline for actually submitting the final report to
11 the NRC?

12 MS. HOLIDAY: I can receive that report no
13 later than March 28th.

14 MEMBER ZANZONICO: Okay, that's fine.

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

17 MS. HOLIDAY: Yes, sir, April 15th and 16th
18 here at headquarters.

19 CHAIRMAN MALMUD: And each of the members
20 of the Committee by now should have had his or her
21 transportation and room arrangements solidified.

22 MS. HOLIDAY: Ideally.

23 CHAIRMAN MALMUD: Ideally. If any member
24 of the Committee who intends to attend the meeting has
25 not done so, I would suggest at this point that you

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1 contact Sophie who might be help you to expedite the
2 arrangements. Is that fair, Sophie?

3 MS. HOLIDAY: Yes, sir.

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

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

15 MS. HOLIDAY: Final document.

16 CHAIRMAN MALMUD: Final document. Thank you
17 very much.

18 MS. HOLIDAY: Yes, sir.

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

20 CHAIRMAN MALMUD: Thank you.

21 MR. EINBERG: Goodbye, everyone.

22 CHAIRMAN MALMUD: The meeting is adjourned.
23 Thank you.

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

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