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Uses of Isotopes

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USE OF ISOTOPES

(ACMUI)

+ + + + +

MEETING

+ + + + +

THURSDAY,

MAY 13, 2004

+ + + + +

ROCKVILLE, MARYLAND

+ + + + +

The Advisory Committee met at 1:00 p.m. via
teleconference, Dr. Leon S. Malmud, Vice Chairman,
presiding.

COMMITTEE MEMBERS:

LEON S. MALMUD, M.D.	Health Care Administrator, Vice Chair
NEKITA HOBSON	Patient Advocate
RALPH P. LIETO	Medical Physicist, Nuclear Medicine
RUTH McBURNEY	State Robinson
SALLY WAGNER SCHWARZ, R.Ph.	Nuclear Pharmacist

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COMMITTEE MEMBERS (cont.):

ORHAN H. SULEIMAN, Ph.D. Food and Drug
Administration
Representative

RICHARD J. VETTER, Ph.D. *Radiation Safety Officer*

JEFFREY F. WILLIAMSON, Ph.D. Therapy Physicist

NRC STAFF PRESENT:

THOMAS ESSIG

*Designated Federal
Officer NMSS/IMNS/MSIB*

ROBERTO J. TORRES NMSS/IMNS

ANGELA R. WILLIAMSON NMSS/IMNS/MSIB

ALSO PRESENT:

DR. CAROL MARCUS

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

1:18 p.m.

VICE CHAIR MALMUD: On the record. Can we start?

FEDERAL OFFICER ESSIG: Yes, if I may, Dr. Malmud.

VICE CHAIR MALMUD: Please do.

FEDERAL OFFICER ESSIG: As designated Federal official, are we on, Mr. Court Reporter?

COURT REPORTER: Yes.

FEDERAL OFFICER ESSIG: Okay. As designated Federal official for this meeting, I'm pleased to welcome you to this publicly-noticed conference call meeting of the ACMUI. My names is Thomas Essig. I'm Branch Chief of Materials Safety Inspection Branch and have been designated as the Federal official for this advisory committee in accordance with 10 CFR Part 7.11.

This is an announced meeting of the committee. It's being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the May 5, 2004 addition of The Federal Register. The function of the committee is to advise the staff on issues and

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1 questions that arise on the medical use of byproduct
2 material. The committee provides counsel to the staff
3 but does not determine or direct the actual decisions
4 of the staff or the commission. The NRC solicits the
5 views of the committee and values them very much.

6 A request that whenever possible we try to
7 reach consensus on the various issues that we will
8 discuss during this conference call, but also value
9 minority or dissenting opinions. If you have such
10 opinions, please allow them to be read into the
11 record.

12 As part of the preparation for this
13 meeting, I have reviewed the agenda for members and
14 employment interests based on the general nature of
15 the discussion that we are going to have today. I've
16 identified the items related to St. Joseph Mercy
17 Hospital dose reconstruction as posing a conflict for
18 Committee Member Ralph Lieto.

19 Because that hospital is Mr. Lieto's
20 current employer, I ask that he not participate in any
21 of the committee's decision making activities, other
22 formal actions, recommendations or conclusions related
23 to the dose reconstruction effort for the St. Joseph
24 Mercy Hospital case. If during the course of our
25 business, other members determine that they have a

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1 conflict of interest in matters before the committee,
2 please state it for the record and recuse yourself
3 from that particular aspect of the discussion.

4 At this point, I would like to perform a
5 roll call of members that may be participating today.
6 I believe Dr. Cerquiera is not with us. Dr. Malmud is
7 present.

8 VICE CHAIR MALMUD: Yes.

9 FEDERAL OFFICER ESSIG: Ms. Hobson is
10 present.

11 MEMBER HOBSON: Yes.

12 FEDERAL OFFICER ESSIG: Ms. McBurney is
13 present.

14 MEMBER McBURNEY: Yes.

15 FEDERAL OFFICER ESSIG: Dr. Egley.

16 (No response.)

17 FEDERAL OFFICER ESSIG: Dr. Diamond.

18 (No response.)

19 FEDERAL OFFICER ESSIG: Dr. Nag.

20 (No response.)

21 FEDERAL OFFICER ESSIG: Ms. Schwarz.

22 MEMBER SCHWARZ: Yes.

23 FEDERAL OFFICER ESSIG: Dr. Vetter.

24 MEMBER VETTER: Yes.

25 FEDERAL OFFICER ESSIG: Dr. Williamson.

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1 MEMBER WILLIAMSON: Yes.

2 FEDERAL OFFICER ESSIG: And Mr. Lieto.

3 MEMBER LIETO: Yes.

4 FEDERAL OFFICER ESSIG: Dr. Suleiman.

5 MEMBER SOLEIMAN: Yes.

6 FEDERAL OFFICER ESSIG: Okay. And I would
7 also like to recognize if they are present any of the
8 newly appointed ACMUI members. Dr. Center (PH).

9 (No response.)

10 FEDERAL OFFICER ESSIG: Dr. VanDecker
11 (PH).

12 (No response.)

13 FEDERAL OFFICER ESSIG: Mr. Bailey.

14 (No response.)

15 FEDERAL OFFICER ESSIG: Okay. For the
16 Court Reporter's benefit, the individuals who are
17 present today are Dr. Leon Malmud, Ms. Nekita Hobson,
18 Ms. Ruth McBurney, Ms. Sally Schwarz, Dr. Richard
19 Vetter, Dr. Jeffrey Williamson, Mr. Ralph Lieto, Dr.
20 Orhan Suleiman. And I now ask NRC staff who are
21 present to identify themselves. I had already
22 mentioned my name is Thomas Essig and with me are?

23 MR. TORRES: Roberto Torres.

24 FEDERAL OFFICER ESSIG: And?

25 MS. WILLIAMSON: Angela Williamson.

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1 FEDERAL OFFICER ESSIG: Okay. Then
2 following the discussion of each agenda item, the
3 Chair at his option may entertain comments or
4 questions from members of the public who are
5 participating with us today. In the absence of the
6 ACMUI Chairperson, Dr. Leon Malmud, ACMUI Vice Chair
7 will conduct today's meeting. Dr. Malmud, I turn the
8 proceedings over to you.

9 VICE CHAIR MALMUD: Thank you. We do have
10 at least one guest on the phone with us and that's Dr.
11 Carol Marcus.

12 DR. MARCUS: Hi.

13 VICE CHAIR MALMUD: Are there any other
14 guests who wish to identify themselves?

15 (No response.)

16 VICE CHAIR MALMUD: Thank you. Let's move
17 on to the draft document, memorandum actually, dated
18 April 29, 2004, subject: Report to ACMUI. The goal of
19 today's meeting, if possible, is to have the ACMUI
20 vote on the DRS report. Specifically we would vote
21 either to forward the report to the NRC staff or not.
22 With that goal in mind, may we begin by looking at the
23 memorandum and asking for comments on each paragraph
24 one by one?

25 First, paragraph 1, the paragraph

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1 beginning "The memo summarizes..." any comments on
2 that? If not, we'll move on to the next.

3 (No response.)

4 VICE CHAIR MALMUD: Thank you. Next
5 paragraph, "Review of Region 3's Dose Calculation
6 Methodology."

7 (No response.)

8 VICE CHAIR MALMUD: Next paragraph. "DRS
9 Findings and Recommendations." That's a lengthy
10 paragraph. It has parts 1, 2.

11 MEMBER J. WILLIAMSON: Would you like me
12 to summarize each part.

13 VICE CHAIR MALMUD: I don't think it's
14 necessary unless there are questions.

15 MEMBER J. WILLIAMSON: Okay.

16 VICE CHAIR MALMUD: But we very much
17 appreciate the offer and not to mention all the effort
18 that you have put into this, Jeff. All right. So
19 we're up to "DRS Findings and Recommendations"
20 subheading one.

21 (No response.)

22 VICE CHAIR MALMUD: No comments.
23 Subheading 2?

24 (No response.)

25 VICE CHAIR MALMUD: Subheading 3 including

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1 the five bullets?

2 (No response.)

3 VICE CHAIR MALMUD: Subheading 4?

4 (No response.)

5 VICE CHAIR MALMUD: Subheading 5?

6 (No response.)

7 VICE CHAIR MALMUD: Subheading 6 including
8 five bulleted items?

9 (No response.)

10 VICE CHAIR MALMUD: Subheading 7 including
11 those bulleted items? There are four.

12 (No response.)

13 VICE CHAIR MALMUD: Subheading 8.

14 (No response.)

15 VICE CHAIR MALMUD: Subheading 9.

16 (No response.)

17 VICE CHAIR MALMUD: And the last paragraph
18 which begins with the words, "In general, DRS believes
19 that ..."

20 (No response.)

21 VICE CHAIR MALMUD: If not, then we move
22 on to the next part of this document which is the
23 appendix.

24 MEMBER: Which one?

25 VICE CHAIR MALMUD: We have Appendix B and

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1 Appendix C.

2 MEMBER McBURNEY: This is Ruth McBurney.
3 There was a technical report and then the comment on
4 Dr. Marcus's deal.

5 VICE CHAIR MALMUD: Yes. That's Appendix
6 C would be the Marcus.

7 MEMBER McBURNEY: C.

8 MEMBER WILLIAMSON: Appendix A is simply
9 the Inspection Report.

10 MEMBER McBURNEY: Right.

11 VICE CHAIR MALMUD: So we'll skip Appendix
12 A if that meets with everyone's agreement since that's
13 a report and move on to Appendix B which is entitled
14 "Technical Report" dated 15 April 2004. Does everyone
15 have a copy of that? If so, are there any comments on
16 Appendix B, "Technical Report," the first paragraph
17 "Interview a region through the inspectors"?

18 (No response.)

19 VICE CHAIR MALMUD: "Then we found that
20 the DRS achieved consensus on the following issues..."
21 which is the second paragraph.

22 (No response.)

23 VICE CHAIR MALMUD: And then there is in
24 bold print the next item "Interview of Ralph Lieto on
25 3/12 and review of SGAH written materials."

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1 (No response.)

2 VICE CHAIR MALMUD: Then there is the next
3 heading which is "Technical Issues."

4 MEMBER LIETO: Could I?

5 VICE CHAIR MALMUD: Please do.

6 MEMBER LIETO: Just clarify one thing
7 there on the interview?

8 VICE CHAIR MALMUD: Who's speaking?

9 MEMBER LIETO: This is Ralph Lieto.

10 VICE CHAIR MALMUD: Thank you.

11 MEMBER LIETO: I just wanted to clarify
12 the second sub-bullet "Other findings."

13 VICE CHAIR MALMUD: Beginning "Based..."

14 MEMBER LIETO: Yes, "Based on
15 recollections..."

16 VICE CHAIR MALMUD: Yes.

17 MEMBER LIETO: It's not my -- I wasn't
18 here, so the claims are -- I would rather it state the
19 "Licensee claims" rather than "I claim."

20 VICE CHAIR MALMUD: Thank you.

21 MEMBER LIETO: Is that acceptable?

22 VICE CHAIR MALMUD: Well, what it says is
23 "Based on recollections of two eye witnesses..." Oh,
24 I see it does say "Mr. Lieto claims..."

25 MEMBER LIETO: Yes.

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1 VICE CHAIR MALMUD: All right. I'm happy
2 to do that.

3 MEMBER LIETO: Actually there's -- Yes.

4 VICE CHAIR MALMUD: That's fine.

5 MEMBER LIETO: Is that okay? I mean -

6 VICE CHAIR MALMUD: Is there any
7 disagreement with substituting that?

8 MEMBER LIETO: There might be the
9 impression that I was the person that was here at the
10 time and that these are my observations and basically
11 I'm just the conduit here.

12 VICE CHAIR MALMUD: Okay. Is there anyone
13 who objects to substituting the term "The licensee"
14 for "Mr. Lieto."

15 (No response.)

16 VICE CHAIR MALMUD: If not, we all agree.
17 That will reread and we'll reprint it as "The
18 licensee."

19 MEMBER LIETO: Okay.

20 VICE CHAIR MALMUD: Thank you, Ralph.

21 MEMBER LIETO: Thank you.

22 VICE CHAIR MALMUD: We then move to
23 "Technical Issues, Effective Half-Life of
24 Reconstructed Distance of Bedside Readings." Any
25 comments on those?

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1 (No response.)

2 VICE CHAIR MALMUD: Thank you. We will
3 then move on to the -- I hear someone breathing as if
4 he wants to say something. Is that you, Jeff?

5 MEMBER WILLIAMSON: Oh, it's just me. As
6 I'm reading this, I'm correcting small misspelling
7 errors and other things, but I'm not making any
8 substantive change.

9 VICE CHAIR MALMUD: If we may then move to
10 the "Summary Statement" which is on page five of this
11 document and has seven bullet points. This is an
12 important summary. May we take these bullet by bullet
13 for your consensus? Bullet 1, everyone agree?

14 (No response.)

15 VICE CHAIR MALMUD: Bullet 2, everyone in
16 agreement?

17 (No response.)

18 VICE CHAIR MALMUD: Bullet 3 which is the
19 first bullet on page 6 which begins "We'll have all
20 the details..."?

21 (No response.)

22 VICE CHAIR MALMUD: Next bullet, "In this
23 particular case"?

24 (No response.)

25 VICE CHAIR MALMUD: The next bullet, "In

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1 contrast to the Marcus Signal (PH) report..."

2 (No response.)

3 VICE CHAIR MALMUD: Next bullet "As
4 suggested by the Marcus Signal (PH) paper..."

5 (No response.)

6 VICE CHAIR MALMUD: Next bullet "The DRS
7 reconstruction effort..."

8 (No response.)

9 VICE CHAIR MALMUD: Therefore, we have
10 just completed Appendix B. It would be helpful if we
11 had a motion from a member of the committee to approve
12 the Appendix B as it is with that one correction.

13 MEMBER VETTER: This is Dick Vetter. I
14 approve Appendix B with that one correction.

15 VICE CHAIR MALMUD: Is there a second?

16 MEMBER SCHWARZ: I second. Sally Schwarz.

17 VICE CHAIR MALMUD: Sally Schwarz seconds.

18 All in favor?

19 (Chorus of ayes.)

20 VICE CHAIR MALMUD: Any opposed?

21 (No response.)

22 VICE CHAIR MALMUD: Any abstentions?

23 MEMBER LIETO: I have one abstention.

24 VICE CHAIR MALMUD: Mr. Lieto abstains.

25 All others approve. Thank you. If we may, we'll move

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1 on to Appendix C. This is entitled "ACMUI Dose
2 Reconstruction Subcommittee (DRS): Comments on Nuclear
3 Regulatory Commission Absorbed Dose Reconstruction for
4 Family Member of I-131 Patient prepared by Drs. Carol
5 Marcus and Jeffrey Segal." This is arranged as a
6 table. There are two pages. If you meet with
7 agreement, we'll go through it item by item, the first
8 being the Marcus-Segal Comment. "We believe that it's
9 imperative to reconstruct the distance before you
10 reconstruct the dose." Any comments about the comment
11 or the response?

12 (No response.)

13 VICE CHAIR MALMUD: Next item, "The
14 Bedside distance." Any comments on either of the
15 right-hand or left-hand boxes discussing the bedside
16 distance?

17 (No response.)

18 VICE CHAIR MALMUD: Next item which is
19 "Evaluating whole body dose." Any comments on either
20 the right-hand or left-hand boxes for that item?

21 (No response.)

22 VICE CHAIR MALMUD: Next item which is
23 "Failing to account for tissue attenuation" left and
24 right. Comments on either of those?

25 (No response.)

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1 VICE CHAIR MALMUD: If not, may we move to
2 the next page where the next item appears and that
3 begins with "Failing to use the line source
4 approximation." Any comment on left or right boxes
5 there?

6 (No response.)

7 VICE CHAIR MALMUD: If not, we'll move on
8 to the next items which is "NRC Estimate of Integrated
9 Bedside DDE Measurement." Comment left or right?

10 (No response.)

11 VICE CHAIR MALMUD: Next item "Based on
12 distance and plausibility." Comment on left or right?

13 (No response.)

14 VICE CHAIR MALMUD: Next and last item
15 which is "Using mean body dose, NRC estimate is too
16 high." Comment on left or right?

17 (No response.)

18 VICE CHAIR MALMUD: That is the last item
19 under Appendix C. May I entertain a motion from the
20 committee for approval of Appendix C as it is written?

21 MEMBER HOBSON: I so move. This is Neki
22 Hobson.

23 VICE CHAIR MALMUD: Thank you. Neki
24 Hobson makes the motion. Is there a second?

25 MEMBER VETTER: Dick Vetter seconds.

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1 VICE CHAIR MALMUD: Dick Vetter seconds.

2 All in favor?

3 (Chorus of ayes.)

4 VICE CHAIR MALMUD: Any opposed?

5 (No response.)

6 VICE CHAIR MALMUD: No opposition. Is
7 there an abstention?

8 MEMBER LIETO: One abstention. Ralph
9 Lieto.

10 VICE CHAIR MALMUD: Ralph Lieto abstains.
11 We have now covered the document and then the
12 appendices.

13 MEMBER VETTER: Dick Vetter. I move
14 approval of the document.

15 MEMBER SCHWARZ: And I second it. Sally
16 Schwarz.

17 VICE CHAIR MALMUD: All in favor?

18 (Chorus of ayes.)

19 VICE CHAIR MALMUD: Any opposed?

20 (No response.)

21 VICE CHAIR MALMUD: Abstentions?

22 MEMBER LIETO: One abstention. Ralph
23 Lieto.

24 VICE CHAIR MALMUD: Thank you. So the
25 memorandum to the full ACMUI with the appendices has

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1 been approved by the full committee with unanimity
2 except for one abstention. Tom?

3 FEDERAL OFFICER ESSIG: Yes, I'm sorry.
4 I was having a sidebar conversation with one of my
5 staff. Go ahead.

6 VICE CHAIR MALMUD: Tom, may I ask you
7 what you would like as the next item on the agenda?

8 FEDERAL OFFICER ESSIG: I believe the next
9 item you've moved and seconded and voted on submitting
10 the report with appendices.

11 VICE CHAIR MALMUD: Yes, we went over each
12 item in the report and each item in the appendices.

13 FEDERAL OFFICER ESSIG: Fine.

14 VICE CHAIR MALMUD: And approved the
15 entire document and specifically we would now like to
16 forward the ACMUI report to the NRC staff.

17 FEDERAL OFFICER ESSIG: Okay.

18 VICE CHAIR MALMUD: Shall we have a
19 separate motion to do that? We just approved it. I
20 would assume that it includes forwarding it, but just
21 to be specific, I'm to entertain a motion that we
22 forward this to the NRC staff.

23 FEDERAL OFFICER ESSIG: Sure. That would
24 be in order.

25 VICE CHAIR MALMUD: Which member of the

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1 committee wants to make that motion?

2 MEMBER J. WILLIAMSON: Okay. Jeff
3 Williamson here. I move that we forward the approved
4 report to the NRC staff.

5 VICE CHAIR MALMUD: Is there a second to
6 the motion?

7 MEMBER SOLEIMAN: I second. Orhan.

8 VICE CHAIR MALMUD: Thank you. It's been
9 moved and seconded. Any discussion?

10 (No response.)

11 VICE CHAIR MALMUD: All in favor?

12 (Chorus of ayes.)

13 VICE CHAIR MALMUD: Any opposed?

14 (No response.)

15 VICE CHAIR MALMUD: Any abstention?

16 MEMBER LIETO: One abstention. Ralph
17 Lieto.

18 VICE CHAIR MALMUD: Thank you. There's a
19 consensus for approval with one abstention of Mr.
20 Lieto. That covers the approval and the
21 recommendation to forward this to the NRC staff.

22 FEDERAL OFFICER ESSIG: And, Dr. Malmud,
23 this is Thomas Essig. I believe that Angela
24 Williamson of my staff had previously shared with you
25 the guidance for preparation of the memo and the use

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1 of the new ACMUI letterhead for submittal to us.

2 VICE CHAIR MALMUD: Yes, you had.

3 FEDERAL OFFICER ESSIG: Okay. And then
4 you may sign it as Acting Chairman of the committee in
5 the absence of Dr. Cerqueira.

6 VICE CHAIR MALMUD: So then this will be
7 reprinted on NRC stationary meaning the ACMUI
8 Committee stationary and forwarded.

9 FEDERAL OFFICER ESSIG: Yes.

10 VICE CHAIR MALMUD: That will occur
11 tomorrow as my secretary is out now for the afternoon.

12 FEDERAL OFFICER ESSIG: That will be fine.
13 And we would ask that if possible that we send it
14 either by Express Mail or FedEx or one of the services
15 like that so we have it by Monday.

16 VICE CHAIR MALMUD: Right. May I ask that
17 Angela contact Patricia tomorrow? Angela?

18 MS. WILLIAMSON: Certainly, I will.

19 VICE CHAIR MALMUD: Thank you. That will
20 make sure that it happens. Is there any other
21 business to occur in the course of this meeting?

22 FEDERAL OFFICER ESSIG: Mr. Chairman, at
23 your option, you may entertain comments or questions
24 from any members of the public who are participating
25 with us today.

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1 VICE CHAIR MALMUD: I am pleased to do so.
2 Are there any comments from any members of the public
3 who are with us today?

4 DR. MARCUS: Just one request from Carol
5 Marcus.

6 VICE CHAIR MALMUD: Yes.

7 DR. MARCUS: I believe that material that
8 is discussed by the ACMUI in a public meeting is
9 available to be read by members of the public who are
10 at the meeting. Because it's a telephone meeting, I
11 have not seen the document that you have discussed at
12 your meeting and I wondered if someone could email it
13 to me.

14 MS. WILLIAMSON: I will email that to you,
15 Dr. Marcus. This is Angela Williamson.

16 DR. MARCUS: Okay. You have my email
17 address, Angela?

18 MS. WILLIAMSON: I do.

19 DR. MARCUS: Okay. Great. I appreciate
20 that.

21 VICE CHAIR MALMUD: The minutes will
22 reflect that Angela Williamson has committed to
23 emailing a copy of the document to Dr. Marcus. Thank
24 you. Any other business to come before this
25 committee?

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1 (No response.)

2 VICE CHAIR MALMUD: If not, is there a
3 motion for adjournment of the committee?

4 MEMBER VETTER: So moved.

5 VICE CHAIR MALMUD: I'm sorry. Who made
6 the motion?

7 MEMBER VETTER: Dick Vetter.

8 VICE CHAIR MALMUD: Dick Vetter made the
9 motion.

10 MEMBER SOLEIMAN: I second. This is
11 Orhan.

12 VICE CHAIR MALMUD: Thank you. I assume
13 that there's a consensus on ending the committee
14 meeting. I want to thank you all both for the
15 efficiency of this meeting as well as for the enormous
16 amount of work that I know a number of you have put
17 into preparing, reviewing, revising this document in
18 preparation of submission to the NRC and I also wish
19 to thank Dr. Marcus as a member of the public for
20 being one of the stimuli for having reviewed this
21 document. Thank you all. Off the record.

22 *(Whereupon, the above-entitled matter was*
23 *concluded at 1:37 p.m.)*

24

25

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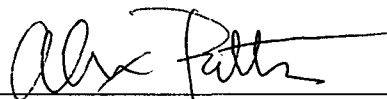
This is to certify that the attached proceedings
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in the matter of:

Name of Proceeding: Advisory Committee on the
Medical Uses of Isotopes

Docket Number: n/a

Location: telephone conference

were held as herein appears, and that this is the
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thereafter reduced to typewriting by me or under the
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transcript is a true and accurate record of the
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Alex Patton
Official Reporter
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