Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Advisory Comn	nittee on the Medical Uses of Isotopes
Docket Number:	N/A
Location:	Teleconference
Date:	January 12, 2011

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

NRC-658

Pages 1-75

Work Order No.:

UNITED STATES OF AMERICA NUCLEAR REGULATORY COMMISSION + + + + + ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES + + + + + TELECONFERENCE + + + + + WEDNESDAY, JANUARY 12, 2011 9 10 + + + + + The meeting was convened, at 1:00 p.m. Eastern 11 Standard Time, Leon S. Malmud, M.D., ACMUI Chairman, 12 presiding. 13 14 MEMBERS PRESENT: LEON S. MALMUD, M.D., Chairman 15 BRUCE THOMADSEN, Vice Chairman 16 DR. DARRELL FISHER 17 MS. DEBBIE GILLEY 18 19 DR. MILTON GUIBERTEAU, DR. SUSAN LANGHORST 20 21 MR. STEVE MATTMULLER DR. CHRISTOPHER PALESTRO 22 DR. WILLIAM VAN DECKER 23 24 DR. JAMES WELSH 25 DR. PAT ZANZONICO **NEAL R. GROSS**

COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

ı	
1	2
2	NRC STAFF PRESENT:
3	ROB LEWIS - Division Director
4	MICHAEL FULLER - Alternate Designated Federal Officer
5	ASHLEY COCKERHAM - ACMUI Coordinator
6	DR. DONNA BETH HOWE
7	GLENDA VILLAMAR
8	GRETCHEN RIVERA-CAPELLA
9	DR. SAID DAIBES
10	JUNE CAI
11	SUSAN CHIDAKEL
12	SANDY GABRIEL - REGION 1
13	MARYANN ABOGUNDE - REGION 1
14	SARA FORSTER - REGION 3
15	
16	MEMBERS OF THE PUBLIC:
17	LYNNE FAIROBENT, American Association of Physicists ir
18	Medicine
19	RALPH LIETO, St. Joseph Mercy Hospital
20	MIKE PETERS, American College of Radiology
21	MICHAEL SHEETZ, University of Pittsburgh
22	CINDY TOMLINSON, American College for Radiation

NEAL R. GROSS

23

24

Oncology

1	TABLE OF CONTENTS	
2	Opening Remarks, Mike Fuller, Alternate Designated	
3	Federal Officer	4
4	Roll Call of the ACMUI Members	5
5	Introduction of NRC Staff Members	7
6	Introduction of Participants from Regional Offices	7
7	Introduction of Members of the Public	7
8	ACMUI Reporting Structure	9
9	Comments of Members of the Public	51
10	Adjournment	75

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

1:00 p.m.

MR. FULLER: Okay, as the alternate Designated Federal Officer for this meeting, I am pleased to welcome you to this teleconference meeting of the ACMUI. My name is Mike Fuller. I am the team leader for the Medical Radiation Safety Team and I have been designated as the alternate Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

This is an announced meeting of the It is being held in accordance with the Committee. rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission. The meeting was announced in the December 21st, 2010 edition of the Federal Register.

The function of the Committee is to advise the staff on issues and questions that arise on the medical use of byproduct material. The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission.

NRC solicits the views of the Committee and values their opinion. A request that whenever possible we try to reach consensus on issues that we

NEAL R. GROSS

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

1	will discuss today, but I also recognize that there
2	may be minority or dissenting opinion. If you have
3	such opinion, please allow them to be read into the
4	record.
5	At this point, I would like to perform a
6	role call of the ACMUI members participating today.
7	When I call your name, please indicate if
8	you are present.
9	Dr. Leon Malmud.
10	CHAIR MALMUD: Present.
11	MR. FULLER: Dr. Bruce Thomadsen.
12	VICE CHAIR THOMADSEN: Present.
13	MR. FULLER: Dr. Darrell Fisher.
14	MEMBER FISHER: Present.
15	MR. FULLER: Ms. Debbie Gilley.
16	MEMBER GILLEY: Present.
17	MR. FULLER: Dr. Mickey Guiberteau.
18	MEMBER GUIBERTEAU: Present.
19	MR. FULLER: Dr. Sue Langhorst.
20	MEMBER LANGHORST: Present.
21	MR. FULLER: Mr. Steve Mattmuller.
22	(No response.)
23	MR. FULLER: Dr. Christopher Palestro.
24	MEMBER PALESTRO: Present.
25	MR. FULLER: Dr. John Suh.

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701 (No response.)

2

3

4

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MR. FULLER: I will note that Dr. Orhan Suleiman has notified the ACMUI Chairman and NRC that he will be unable to participate today.

Dr. William Van Decker.

(No response.)

MR. FULLER: Dr. James Welsh.

MEMBER WELSH: Here.

MR. FULLER: Dr. Pat Zanzonico.

MEMBER ZANZONICO: Yes.

MR. FULLER: Okay.

MEMBER MATTMULLER: Hi, this is Steve Mattmuller. If you're doing roll call, I am checking in.

MR. FULLER: Thank you, Mr. Mattmuller. Has either Dr. Suh or Dr. Van Decker joined us yet? Okay.

I'll note that a quorum has been met for the purposes of conducting this meeting. I would also note that Dr. Palestro does not have voting rights at this time, but he will listen and speak on behalf of the nuclear medicine physicians.

I will now introduce the NRC staff members who are present here at NRC headquarters. Again, my name is Mike Fuller. We also have with us Rob Lewis.

NEAL R. GROSS

1	We I'll go around the room here. We have Glenda
2	Villamar. We have June Cai, Dr. Said Daibes, Susan
3	Chidakel, Dr. Donna Beth Howe and Gretchen Rivera-
4	Capella. Also, I believe on the phone we have Ashley
5	Cockerham and are there any other NRC headquarters in
6	attendance by phone today?
7	We will now go to the Regional offices.
8	Do we have any one on the call from Region 1?
9	MS. GABRIEL: Sandy Gabriel.
10	MS. ABOGUNDE: Maryann Abogunde.
11	MR. FULLER: Okay. Region 3.
12	MS. FORSTER: This is Sara Forster.
13	MR. FULLER: Okay, Region 4.
14	(No response.)
15	MR. FULLER: Next will identify members of
16	the public who notified us that they would be
17	participating on the teleconference. When I call your
18	name please answer.
19	Lynne Fairobent, American Association of
20	Physicists in Medicine.
21	MS. FAIROBENT: Present.
22	MR. FULLER: Ralph Lieto, St. Joseph Mercy
23	Hospital.
24	DR. LIETO: Present.
25	MR. FULLER: Jackie Kavanagh, Nordion.

(No response.) MR. FULLER: Mike Peters, American College 2 3 of Radiology. MR. PETERS: Present. Gloria Romanelli, American MR. FULLER: College of Radiology. 6 (No response.) 8 MR. FULLER: Michael Sheetz, University of 9 Pittsburgh. 10 MR. SHEETZ: Here. Cindy Tomlinson, American 11 MR. FULLER: College for Radiation Oncology. 12 MS. TOMLINSON: I'm here. 13 14 MR. FULLER: Is there anyone else on the 15 call that I have not recognized? 16 (No response.) FULLER: At this time I ask that 17 MR. everyone on the call who is not speaking to please 18 19 place their phones on mute. If you do not have the capability to mute your phone please press star 6 to 20 utilize the conference line mute and unmute function. 21 22 I would ask everyone to exercise extreme care to ensure that the background noise is kept at a 23 minimum as any stray background sounds can be very 24 25 disruptive on a conference call this large.

Following the discussion of each agenda item, the ACMUI Chairperson, Dr. Leon Malmud, at his option may entertain comments or questions from members of the public who are participating with us today.

At this point, I'd like to turn the meeting over to Dr. Malmud.

CHAIR MALMUD: Thank you. Today, we have a one-item agenda today and the one item on the agenda

a one-item agenda today and the one item on the agenda is entitled ACMUI Reporting Structure. I believe that you have all received a copy of the document dated January 7 entitled "ACMUI Reporting Structure Background Information."

Is there a member of the ACMUI who has not received that?

(No response.)

Hearing no response, I assume that we have all received it and that is the item for discussion. Would a member of the Committee care to initiate the discussion of the item?

MEMBER ZANZONICO: This is Pat Zanzonico.

CHAIR MALMUD: Thank you.

MEMBER ZANZONICO: I've read Ashley's document. It was very well done, very clear, very informative and my personal opinion is that frankly I

NEAL R. GROSS

2

3

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

don't really have a strong preference between the items, between the options suggested rather. I think the current arrangement seems to work well, especially Dr. Malmud, given your experience and really assurances of access as needed of the ACMUI to the Commissioners. I think given that, personally I don't see a tangible advantage, a tangible benefit to changing the current arrangement to that of the other Committees.

My brief experience, admittedly, on the ACMUI it seems to work well. The interactions with the staff seem to be cordial, productive, effective, etcetera, etcetera. And as I said, given your experience in terms of the Commissioners themselves as needed, I would endorse the status quo.

CHAIR MALMUD: Thank you, Pat. May we hear comments from other members of the Committee regarding the item on the agenda?

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

CHAIR MALMUD: Yes, Sue.

MEMBER LANGHORST: I very much appreciate the Committee's indulgence on tabling this item and giving us a little more time to look at things and I appreciate the draft report that Ashley provided us.

NEAL R. GROSS

At the direction of the Commission, the staff was asked to work with the Office of the General Counsel to provide the Commission a paper that outlines possible improvements, improved mechanisms for providing the Commission with ACMUI's feedback regarding medical issues. I think that is our new operating procedure that we approved in December at our teleconference.

And this paper then is also to include the pros and cons of restructuring ACMUI's reporting structure and that is part of what Ashley is drafting and to provide an implementation plan that would be used to make that change. And again, I think that's part of Ashley's draft.

So I've been thinking about this quite a bit this past week and really was trying to come up with not only what the Commission is asking the staff to do at this point in time, but what are the questions that this review is trying to answer or maybe should it be trying to answer.

Now I've come up with a list of questions that have come to my mind, but this is by far not inclusive of everything. Here are the questions that have come to my mind. How do or should the Commissioners get their information on medical uses to

NEAL R. GROSS

make their decisions? How do or should the NRC staff, medical use medical staff have access to current medical expertise? How do or should the ACMUI offer their questions and comments the up Commissioners and the NRC staff?

How do or should the medical community, and here I mean licensees and organizations of those types of licensees, offer up their questions and comments to the Commission, the NRC staff and ACMUI? How should the perspectives of each of these groups, and in this case I mean the Commission, NRC staff, NRC medical use staff, ACMUI, the medical community, Agreement States, patients and patient groups, and the public, how should they be considered in how and where the ACMUI functions?

And then my final question is what are the logical -- excuse me, the logistical pros and cons for the ACMUI reporting to NRC medical use staff and the option of reporting to the Commission?

Now I think these may or may not be questions we're trying to ask and answer in a review such as this, but I would ask the Committee if this is an opportunity to look at some of these questions and maybe it should be a continual process of looking at these types of questions on how we're functioning at

NEAL R. GROSS

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

any given point in time. Thank you.

CHAIR MALMUD: Thank you, Sue. So there are six questions that you've raised. And I believe that they summarize the concerns that have been expressed by one or more members of the Committee and others with regard to the current structure.

Are there any other comments with regard to the six questions that Sue has raised, or any other issues from the members of the Committee?

MEMBER GILLEY: Dr. Malmud, this is Debbie Gilley. I concur with all of Dr. Langhorst's questions and I guess my concern coming as the Agreement State representative what impact would the ACMUI reporting to the Commission versus reporting to FSME would have on the relationship with the Agreement States?

CHAIR MALMUD: Okay, we'll consider that a seventh issue, if that's acceptable to Sue.

MEMBER LANGHORST: Yes, and that was my intent to be inclusive of some of our recommendations may have impacts to Agreement States in one of my —this question, so I apologize, Debbie, I didn't get that quite right. Not that we're advising the Agreement States, but they certainly have a stake in this whole issue, too.

NEAL R. GROSS

CHAIR MALMUD: Thank you. Hearing no other comment immediately, I would then offer the following in summary.

Currently, the ACMUI consults to staff, which then delivers the opinions of ACMUI to the Commission. We also currently have direct access to the Commissioners at our request for a so-called drop-in, if necessary. We have not availed ourselves of the latter opportunity with great frequency although my last visit with three of the Commissioners and one staff member representing another Commissioner indicated that we always have that option available to us.

In the past, with previous Commissioners and a previous chair of the Commission, we were asked to have a significant agenda, three items or more, in general, when dealing with the Commission. That no longer applies. We can bring one critical issue before them, if necessary.

The second issue was that there was concern in the past by members of the ACMUI who are not currently members of the Committee, but who may be representing members of the public on the call today, with regard to making certain that the opinions that were rendered by the ACMUI were transmitted to the

NEAL R. GROSS

Commissions in an unfiltered manner. I don't believe that we currently feel that this is an issue, but it was an issue in the past and therefore, it might become an issue in the future, since we can't predict the future.

The third issue is the reporting lines and I think that those are pretty clear the way they are right now. But the concern was, was there a way of recommendations in terms of up our process because very often discussions take recommendations may several years between initiation of the discussion and implementation rejection of the recommendation by the Commission itself.

The latter issue I have always believed is related to the frequency of our meetings, rather than to any delay on the part of staff. And we, of course, have the option of - with proper notice to the public - calling meetings by telephone, rather than simply limiting our activities to the two meetings that we hold physically at NRC headquarters annually.

So some of the issues remain. Some of the issues do not. And some of the issues are only of concern in terms of their potential for recurring, if you will.

NEAL R. GROSS

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

We also have a different staffing now, a different relationship between the ACMUI staff. We're very fortunate in our relationships and staffing. So those members of the Committee who are new have not necessarily experienced the concerns that those members in the past experienced. However, there's always the potential for recurring problems and I assume that the reason for continued consideration of changing the reporting line is not with respect to current practices, but with respect to past concerns and concern about the future. once again ask members of the Committee if they have any further comments with regard to the document that

Having made that statement, I would then was distributed and a recommendation.

VICE CHAIR THOMADSEN: Dr. Malmud?

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: It's Bruce Thomadsen.

CHAIR MALMUD: Yes.

VICE CHAIR THOMADSEN: And my only comment on the document is that the Option 2 where it talks about reporting directly to the Commission, I'm not sure that the organization that's laid out there is

NEAL R. GROSS

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

17 the only possible organization and that other possible organizations might be more beneficial, both to the Commission and to the operation of the Committee. some of the potential cons I'm not sure would actually That as being actual cons. would not out necessarily be the case on that. I only point that out as we consider the options that -- the option as stated directly there may not be the only thing that we should consider. CHAIR MALMUD: Thank you. Do you have a suggestion for a third option? VICE CHAIR THOMADSEN: I would think that

VICE CHAIR THOMADSEN: I would think that a third option as far as potential organizations would be best worked out with a combination of the ACMUI working with staff to look at the possible options. The organizational structure of the NRC is a bit byzantine and for somebody who is not in the organization to try to state what it should be would be very difficult without a guide.

All that being said, I find myself having very strong feelings of ambivalence towards making any changes right now.

CHAIR MALMUD: Thank you. Other comments from members of the Committee?

MEMBER WELSH: Yes, Dr. Malmud. Jim

NEAL R. GROSS

2

3

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

Welsh.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

CHAIR MALMUD: Dr. Welsh.

I have similar kinds of MEMBER WELSH: just feelings to what Bruce has mentioned regarding the listed cons on Option 2, I would like a little bit more feedback so that I understand just how real these potential cons are. What Bruce has just mentioned that some of the cons may not pan out to be genuine could be a concern. As an example, I would like to ask about number 3 on cons for Option 2, potential reduced FSME staff access to ACMUI members as medical consultants due to conflict of interest.

Can somebody please explain to us what that means if we report to the Commission as opposed to the present situation, how would we have new conflicts of interest that would limit our ability to serve as consultants?

CHAIR MALMUD: Thank you for the question.

I'll address it to a member of NRC staff, if I may?

MR. LEWIS: Dr. Malmud, this is Rob Lewis.

I can elaborate on that a little bit. I think that the issue there is really a legal issue and that the Commission, the five Commissioners have an adjudicatory role, so advice that they get on matters that may eventually come before them for decision need

NEAL R. GROSS

to be separated from advice that the staff may And I think that that is the issue. getting. you were say on a Committee and also giving advice to the staff, or being a medical consultant, there would be some conflict of interest issues there. the **ACRS** through the of who reports up Commission, their management doesn't go through the EDO. They report to one SES manager who reports to the Commission.

So we would have to follow a model like that and the staff would have to obtain its own independent medical expertise for developing issues to send up to the Commission. We have medical expertise, of course, but we would want the expertise of physicians as we use you today to get.

CHAIR MALMUD: Thank you. Does that answer the question that was raised?

MEMBER WELSH: I believe it does, but I suppose a follow-up question might be how often and what proportion of medical consultations would be indicated by this change in reporting structure? Five percent or is it going to be the majority or all of the potential access to the medical consultation? How significant is this problem?

CHAIR MALMUD: Dr. Welsh raises the

NEAL R. GROSS

2

3

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

question.

MR. LEWIS: I'm sorry, he was breaking up a little bit, but I believe it is significant. It would be -- the staff will get its own medical expertise and the Commission would have availability to the ACMUI expertise if they reported to the Commission. So we would completely separate the roles.

VICE CHAIR THOMADSEN: Dr. Malmud?

CHAIR MALMUD: Yes, Dr. Thomadsen.

VICE CHAIR THOMADSEN: I have a question for Mr. Lewis. Is this a problem that comes up all the time in the reactor world?

MR. LEWIS: Is what a problem?

VICE CHAIR THOMADSEN: Does the NRC staff have to get their own reactor consultants rather than using the Reactor Committee as an advisory body?

MR. LEWIS: In effect, yes. Because what happens is the staff, much like we do with this Committee, the staff makes a presentation to the Committee. In that case, the Committee will react to it through a letter written to the Chairman of the NRC. And that will come down through the EDO which the staff will respond to it without using the Committee as a resource, using its own resources. And

NEAL R. GROSS

then the responses go back and forth up through the So it is separated. 2 EDO level. And the ACRS gives policy advice directly 3 to the Commission in effect, not directly to the 4 staff. CHAIR MALMUD: Thank you for clarifying 6 Does that answer your question? 8 VICE CHAIR THOMADSEN: Ιt Oh yes. 9 certainly does. Thank you very much. 10 CHAIR MALMUD: Thank you. 11 MEMBER GUIBERTEAU: Dr. Malmud? 12 CHAIR MALMUD: Yes. 13 MEMBER GUIBERTEAU: This is Mickey 14 Guiberteau. CHAIR MALMUD: Yes, Mickey. 15 16 MEMBER GUIBERTEAU: I appreciate 17 opportunity to discuss this further. I think tabling this just to receive your comments today and 18 19 experiences well as this reporting as structure 20 background was worth waiting an extra week. 21 With regard to the report, I mean there 22 are two issues addressed in here, large issues. is really the reporting structure in terms of how we 23 24 may best have our voices heard as ACMUI so that the 25 NRC can, in serve the medical community turn,

effectively.

The second is, I believe, operational which has been addressed here and that's how the Committee can best function and be efficient in basically serving the NRC so that it can serve the public and the medical community.

Under the two options given, under the pros, there is a note saying that number one, under the FSME option, use existing staff and then a note is made that ACMUI has requested additional technical and administrative staff support for interactions with the Committee due to increasing work load. And under Option 2, under pros, it has enhanced ACMUI access to facilities and support staff.

I guess my question is if we pursue Option

1, that is the existing reporting structure that has been enhanced in terms of some modifications to it, in response to ACMUI concerns, what is the likelihood that ACMUI could benefit by having additional technical and administrative staff support because that question, it's just stated as a statement without any comment?

CHAIR MALMUD: Thank you for raising the question. Would anyone from NRC staff care to respond? Perhaps Ashley?

NEAL R. GROSS

MR. LEWIS: It's Rob. I can respond.

CHAIR MALMUD: Directly to you, Rob. Thank you.

MR. LEWIS: The likelihood of additional technical support is, it is a possibility. I think that we are currently working on our 2013 budget and the way that we budget, as all the agencies do, we have three budgets in process at any given time. The one that you're executing, the one that Congress is looking at, and the one for the year after that. So we currently have just started working on the 2013 budget.

As you must have heard in the news, the prospect of growing budgets across agencies is not very good in today's climate. So that will be a challenge. However, at the unit level, the allocation between the medical group and the industrial group, while as a whole it may need to stay the same, we do have some leeway to make adjustments within those that keep the zero-sum gain in the more macroscopic way.

So I do think that what we have presented here is just an opinion and we would need to back the opinion up with some assumptions of why or levels of effort, but if that can be done either by the Committee or by Ashley and Radioactive Materials

NEAL R. GROSS

Safety Branch staff and brought forward through the budget process, those types of things do have a good chance of surviving as they go up the chain.

So it is a real possibility to -- in sum, it is a real possibility to get additional technical help at the staff level. We have to demonstrate the need all the way up through the management chain and eventually through Congress and the next real opportunity always lags by a couple of years. So for example, the FY13 budget would be where it would show up today.

CHAIR MALMUD: Thank you for clarifying that. If I may raise a question, in looking at the two structures, it seems to me that the less costly one is the current one with some additional staffing support, that the other model is more costly. Am I correct in that?

MR. LEWIS: Agency-wide, I would agree, yes.

CHAIR MALMUD: And then given the current mood in Washington with regard to budgets over all, the more likely to be approved, although it's not a reason to make the decision, but the more likely to be approved is the first option, given the costs involved in Option 1 versus Option 2.

NEAL R. GROSS

MR. LEWIS: If costs were the only factor, but I wanted to start -- I was going to make an opening comment, but I didn't. And I think if the Committee has a view, regardless of costs, if the Committee has a view about functionality or efficiency or getting the recommendations done sooner as you mentioned, Dr. Malmud, I think that whatever the Committee comes up with, its position will be weighed heavily by the Commission.

CHAIR MALMUD: Thank you.

MR. LEWIS: I don't want to pre-judge what they would predict, but if the Committee took a strong view, they would take it to heart, I'm sure.

CHAIR MALMUD: Thank you. Other comments?

MEMBER FISHER: Dr. Malmud, Darrell
Fisher.

CHAIR MALMUD: Yes.

MEMBER FISHER: I'm a proponent of Option

1 for the Committee structure, but I do have one
concern and that has to do with matters that come
before the Committee, generated by offices other than
the Office of Federal and State Materials and
Environmental Management Programs. Two examples are
matters of radioactive material transportation and the
other one is the obvious issue that we dealt with on

our last conference call, nuclear material safety and safeguards, the safeguarding of Category 1 and Category 2 materials.

So my question is with the current reporting structure, does the Advisory Committee have adequate input to the work of the Nuclear Regulatory Commission in those offices outside FSME?

CHAIR MALMUD: That's the question?

MEMBER FISHER: Yes.

CHAIR MALMUD: Are you asking the Chairman that question or are you asking staff? I could answer the question from my perspective. Maybe we should both answer the question.

MEMBER FISHER: Yes. That would be good, because that's my principal concern. And I've had some input from people outside of the NRC who have viewed the operations of the Advisory Committee for many years and almost unanimously the outside commentators say that the Committee should report in at a higher level and directly to the Commission.

However, since I joined the Committee almost four years ago, I've seen the current reporting structure works very well. So I would like to know whether or not the Committee has adequate input to relevant rulemaking that takes place in parallel

NEAL R. GROSS

organizations.

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

CHAIR MALMUD: Well, I'll give you my opinion, having a little longer tenure on the Committee than most members. I think that our access today is better than it ever has been and that our staff support today is better than it ever has been, without being critical of staff support in the past.

In addition, I must say that my meetings individually, one on one with the Commissioners was an epiphany in a sense in that I was astonished at how well versed each of them was in the discussions that They are aware of the have been ongoing in ACMUI. And they have a very large portfolio. yet, each individual seems quite familiar with the items that I brought forth which were the items that the Committee asked me to bring forth individual members of the Commission. So that I don't feel that we have a problem currently, but I would also have to say that perhaps part of the issue, part of the concern was that we did not avail ourselves of the opportunity of going directly to the Commissioners in the past if we felt the need. And I would assume part of the responsibility for that.

However, in my role as Chairman, it's quite clear that it's available to us and that the

NEAL R. GROSS

Commissioners are well versed in the issues that we've been dealing with. So I don't personally feel the need for a change. However, I also remember what the relationships were when I first joined the Committee and I respect the opinions of those who were concerned about the communication problems at that time. I think though that they have been addressed, at least to my satisfaction. I am only speaking as an individual in this case, and not as the Chairman of the Committee, and therefore I welcome the opinion of any current members of the Committee first, and then we can hear comments from others as well.

Are there any other members of the Committee who feel strongly in favor of Option 2, rather than Option 1? All the comments I've heard thus far seem to be in favor of Option 1.

MEMBER WELSH: Dr. Malmud?

CHAIR MALMUD: Yes.

MEMBER WELSH: Jim Welsh again. I don't necessarily feel very strongly in favor of Option 2, however, I should point out that in my opinion the current mechanism that we have is working out very well. But if you look at it carefully, it is a game of telephone, where we are reporting to maybe four, five or six individuals who then ultimately get the

message to the Commissioners. It's working very well, but I think as you point out, it might be working out presently because we are blessed with some very receptive and competent individuals. And that may not always be the case.

And therefore, one has to ask the question of is this working well now because of the individual people involved or is it working out well for us now because the structure is not broken? I'm not sure I have the answer to that. I suspect that we are blessed with some very qualified individuals and we might be under estimating the importance of their meaningful contribution and confusing that with the system that truly works efficiently and well. And therefore, I think that I still have some feeling that Option 2 may be a better long-term solution. I don't feel strongly about them, but I thought I'd raise that point.

CHAIR MALMUD: Thank you, Dr. Welsh. It might be useful if a member of NRC staff pointed out the difference in time commitment under Option 2 in terms of requiring our physical presence in the Washington area.

Does anyone care from NRC staff to comment on what that would be under Option 2? Perhaps I

NEAL R. GROSS

should raise it as a question. How often does the ACRS meet and what are their -- what's the frequency of their meetings and the time commitment.

MR. LEWIS: The ACRS meets -- this is Rob
Lewis. The ACRS meets once a month for a week, at
least three days, but I think a lot of times for a
week, once a month. I think ten times a year,
actually. And that's actually a tricky question to
answer. I think that the better way I would answer is
if the Committee, the ACMUI was to have as a goal the
same level of involvement that they have today --

CHAIR MALMUD: Yes.

MR. LEWIS: I believe because of the formality of the communications between the staff and the Committee and going through the Commission by letters, I think that for the same level of involvement Option 2 probably would have more resources and therefore more meetings.

CHAIR MALMUD: Thank you for that response. That's what I was expecting that you would say. And I would point out that for the members of the ACMUI who are in medical practice, who are still actively practicing, that would be a significant time commitment away from their primary source of income and professional activity to spend in the District

NEAL R. GROSS

area. And I wonder if the members of the ACMUI are aware of that. I don't know what the answer to the question is, but I hope that you are now aware of the potential for additional time commitment if we were to report under Option 2.

From a personal perspective, given my current status, my home base, I could afford the time, but I know that had I still been in busy practice as I was some years ago, I would have to have declined the opportunity. I don't know how each of you feel. That's a significant time commitment.

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

CHAIR MALMUD: Yes.

MEMBER LANGHORST: I think that's part of the logical question that I raised and I don't think that we could function in exactly the same way that we do right now. I agree that that would be the case. But there may be other ways that that type of interaction could be structured. That's part of what I was raising as far as what would be the logistical pros and cons of this. And just to clarify my stance on things, I think I'm kind of on the same page as Dr. Fisher and Dr. Welsh in this regard. I don't have a strong sense that things need to change and go to

Option 2, but I think it's a very worthwhile exercise to see what is -- what the expectations are of the Commission, the staff, the medical community and help us to meet those expectations.

So I think this is a healthy discussion and I think it should be more than just between the NRC staff and ACMUI. I will be very interested to see how the Commission gives us feedback on this.

CHAIR MALMUD: Thank you. The reason I raised the question of time commitment was so that we would be able to begin to address one of the questions that you raised which was a relevant question and that is would this require significantly more time, not only from NRC staff or staffing, but from the ACMUI members and would it therefore limit the candidates for the ACMUI based upon the individuals' commitments to their home base and their inability to spend that much time perhaps up to three days a month, ten times involvement with the Committee's vear in the activities in Washington.

VICE CHAIR THOMADSEN: Dr. Malmud?

CHAIR MALMUD: Yes, sir.

VICE CHAIR THOMADSEN: A question. Bruce Thomadsen. A question for Mr. Lewis. Could you be any more specific as to why with the same level of

NEAL R. GROSS

2

3

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

activity the time commitment would be so much more?

MR. LEWIS: Yes. I think I can. The first part of that is I think that in the ACRS meetings, they have a letter-writing session every meeting. So in order to produce their positions, they create letters and then send them forward. And that's very time consuming.

I think as Dr. Langhorst said, that's not necessarily saying that this Committee would have to operate the same way. And I do think that because of the -- the second point I would say about what takes more time in that kind of scenario is because the reporting structures are farther apart, the NRC staff presentations the Committee to and then the Committee's feedback to the staff is much more formal and takes more time on our side and does not tend as to get into the level of detail that I've observed at ACMUI I'd like to get into.

The ACMUI works at a lower level of detail about individual medical events or issues than the ACRS does. And I think works well. And I made my statement based on if you wanted to continue that, there would be a multiplication factor of workload to filter those up and down the chain to formal letters all the time. If that helps -- and I do agree

NEAL R. GROSS

2

3

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

completely with Dr. Langhorst that other models could be explored to have ACMUI involved.

If the Commission were to vote and decide that the ACMUI should report to them, we will have to develop an implementation plan to transition and things like the workload on the Committee members, the workload on the staff, what things staff have to separate themselves from, all those issues would have to be part of that plan.

I would not imagine that -- it could happen this way, but I would not imagine that the Commission will say starting tomorrow, the ACMUI reports to us. They would probably give us a year or maybe even longer to transition it. And we'd have to work with you through all those details.

VICE CHAIR THOMADSEN: Thank you.

MEMBER WELSH: Can I ask does anybody have a feeling about which direction the Commission is leaning? Is the Commission seriously considering ACMUI reporting directly to them?

CHAIR MALMUD: This is Dr. Malmud. Would someone care to address Dr. Welsh's question?

MR. LEWIS: Well, I think that -- this is Rob Lewis. I think that's a question for us. I think the Commission asks the staff as a result of the

NEAL R. GROSS

briefing, the medical briefing, to look into this issue. And it was clear to me at that briefing and a briefing before that that at least some of the Commissioners felt that the views of the Committee weren't known to them in having to make a decision on the brachytherapy rule, for example. I should say the views of the Committee weren't fully known to them, and yet the paper was up in front of them. So that was a problem for those Commissioners.

I think that it's a healthy exercise to look at whether the organizational reporting is a part of that problem, whether the organizational reporting and that problem can be unlinked. And I think that's this paper is all about, as well interactions procedure, which is the other paper that was mentioned today. So short answer is no, no one knows exactly what the Commission will do when they the options paper. There will be a staff recommendation in the paper and the Committee welcome to make a recommendation in the paper as well. We will have the Committee views in the paper. recommendation will be just as welcome to put in. they'll take it from there. They'll factor all things in. Our job is to fully inform them. They'll have to decide if the proposals meet their needs, whatever

NEAL R. GROSS

1

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

those needs may be on the medical area.

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

CHAIR MALMUD: Does that answer your question, Dr. Welsh?

MEMBER WELSH: For the most part, it does. do recall the lively discussions of last summer regarding the permanent implant brachytherapy proposed And if I recall correctly, there did seem to be a disconnect between the proposed rule and the ACMUI recommendation. And perhaps that led to a lot of confusion on my part because I and other members of the Implant Brachytherapy Subcommittee, as well as the medical community at large that does this, has very distinct feelings about what a rule should look like. And the proposed rule did not look anything like that. And the Commissioners were put in an awkward position that the re-proposed rule was very different from anything that the ACMUI would endorse or anything that professional organizations would endorse.

And I could understand how this led to confusion about how effectively the Commissioners are receiving ACMUI input. But since then, it seems like things worked far effectively have more and efficiently and Dr. Malmud has pointed out the Commissioners are now quite well briefed on things that we discuss in our Committee. But again, I raise

NEAL R. GROSS

the question of whether it has to do with the individuals involved such as Ashley, Chris, Rob, and Charlie, who have been very receptive and responsive and capable of reporting to the Commission our recommendations and concerns. And if that is not going to always be the case, some folks move on, some folks might retire, move into different positions, and we might not have the same effective chain of communication.

And therefore, I might propose that today I am in favor of maintaining the current reporting structure, but that on an annual basis or something similar, the question should be revisited because today it works. What if it doesn't work next year and we don't revisit this issue for another five years and we're working the next four years with something that is not as efficient as it is today.

CHAIR MALMUD: Thank you. Other comments?

MEMBER MATTMULLER: Dr. Malmud, this is

Steve Mattmuller.

CHAIR MALMUD: Yes, Steve.

MEMBER MATTMULLER: It's my impression and understanding of past interactions of staff and ACMUI that they will really be addressed more effectively through the proposed policy and procedures of 2-5,

NEAL R. GROSS

even perhaps more so than where we're at in the organizational chart. So I'm really pleased to have 2-5 being developed and moving along because I think that will help ensure that things continue to work well.

That said, Darrell raised, Darrell Fisher raised a very good point about issues that aren't under FSME such as nuclear medicines and safeguards. If the FSME Policy 2-5 only affects issues directly controlled by FSME, if there's a non-FSME issue, are we then at risk of having our opinions and thoughts and comments being ignored?

So I guess that's a question for Rob, if I'm interpreting that correctly.

And thank you for bringing MR. LEWIS: that back around because I had a thought when that FSME in my office is the sister division came up. which is DILR, who briefs the Committee every time, all rulemakings within NRC, process except reactor rulemakings. So all of the issues in the NMSS office including transportation or material control and accounting issues, they are processed through FSME in terms of rulemaking and policy. So that procedure will apply to those.

The only thing that the Agency would do

NEAL R. GROSS

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

that the Committee might be interested in that would be outside of that is, of course, reactor and new isotope production kind of issues related to reactor, but that's a new issue to all of us and FSME is following that closely as is the Committee, so I think we, over the last several meetings, have done a good attempt to keep plugged in on that.

But I would go back though to the, you know, the mission of the Committee, of the ACMUI and the charter. And it's to provide -- I don't have it in front of me, but I'm going to summarize and get myself in trouble, to provide advice on the medical policy issues. And a transportation issue that affects a medical licensee, may or may not be a medical policy issue. Of course, we certainly want the Committee to be involved in those and between Josie Piccone and myself, we make sure that those come before the Committee, but I think in terms of the mission of the Committee, it's kind of an indirect relationship. Same goes true for the effect of any Agreement States' compatibility or something. be a medical policy issue, in quotations, but in most cases those are not medical policy issues.

So for the issues that are medical policy issues and things in Part 35 or some of the other

NEAL R. GROSS

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

parts, like Part 20, that are truly and uniquely medical, and we need the expertise of the Committee to give to the Commission, you know, we're obligated to have those go through the Committee and have a very formal back and forth.

For the others, such as transportation of sources, the Committee's role in my mind and under its mission is a less obligatory and formal process, but we certainly want to always involve the Committee in those, if that long, rambling explanation makes any sense.

CHAIR MALMUD: This is Malmud. It makes sense, however, the Committee would feel very strongly in our advisory role if there had been a rulemaking which would have affected transportation therefore limited access of isotopes diagnostic or therapeutic care inadvertently, unknowingly, the Committee would feel very strongly opinion advisory role its and must communicated promptly to the Commission.

MR. LEWIS: I agree. I agree.

CHAIR MALMUD: Is there further discussion of the item on the agenda today?

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

NEAL R. GROSS

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

CHAIR MALMUD: Yes.

MEMBER LANGHORST: I have one just question on the report itself on Option 2. The way that it is drafted right now, is it saying that we would become part of the Agency process or was that not an intended --

CHAIR MALMUD: When I had asked that question, thank you for bringing it forward. When I had asked that question, it wasn't clear to me whether we would be part of that process which concerned me quite frankly because given the amounts of -- if by no other measure, just given the amounts of radioactivity involved, we would be dwarfed in our importance. But if we were in parallel, it would be a larger administrative structure.

Being practical, though I'm not predicting what the Commissioners would say, it seems to me that it would be very expensive to create a parallel organization under Option 2. One of my concerns is that we not be dwarfed in importance because just what — from what I read in the newspaper, we're going to be more heavily involved in expanding our nation's reactor capabilities in the future. So I have the same anxiety you do about the structure of 2 and what options might be selected.

NEAL R. GROSS

Does anyone from NRC staff wish to comment on that?

MR. LEWIS: Yes, in our -- what intended and planned to put in the paper is there will be two separate Committees, continue to but separate Committees would use the same organizational resources. In other words, the current NRC ACRS staff which is, I don't know, 30 people off the top of my head, would be -- and those are all reactor people, by the way. They would need to be supplemented by some NRC staff with medical expertise that would work with But the Committees would not your Committee. merged in any way. One would not be a subcommittee of the other in any way. It's just that the management chain and the secretarial support and all those things would be in the same organization within NRC, but it would be separate from FSME.

CHAIR MALMUD: Does that answer your question, Sue?

MEMBER LANGHORST: Yes, it does. And one more point I want to make is that I totally agree on the Option 1 that there needs to be additional technical and administrative staff support for ACMUI operations.

CHAIR MALMUD: Thank you, I think the

NEAL R. GROSS

2

3

4

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

whole Committee is unanimous on that point.

Is there anyone on the Committee who is not unanimous that if Option 1 is the option, there must be some additional staffing?

(No response.)

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

Hearing response, Ι the no assume Committee is unanimous with respect to that. say as a member of the Committee and not as its Chair, that Option 2 gives me anxiety because we would be joining -- we would be under a management operation which has traditionally been more committed to reactor It would be staffed up, but in a sense, we would be a stepchild within that Committee. addressing any individual. I'm just addressing my experience with being a small organization managed by an organization that manages a large and a small organization. There's never quite equality. And therefore having a separate management, if you will, management commitment has its advantages even though the reporting lines differ a bit. But that's just one man's opinion. I'm not speaking for the Committee in that sense, only from my administrative experience.

Are there other comments from members of the Committee?

MEMBER VAN DECKER: Yes, Dr. Malmud. This

NEAL R. GROSS

is Bill Van Decker. I'd like to weigh in briefly as probably somebody who fits the characteristics of busy and since I only put in an hour for this, I need to be moving on in a moment.

I guess that I personally tend to like enhanced Option 1, being someone who always fears unintended consequences and recognizing what happens in regulatory space of unintended consequences. I'm sure the same is true for this type of situation.

I would point out that I think the key that issue we want here is transparency, early involvement and some proof that the deliberations of the Committee are being sent through as attachments unamended or unplayed with like subcommittee reports and such as part of what's being presented in the interim when we're not together. And I think that the staff has overall done a very good job with some very complicated topics in this regard. And there's always going to be a little fallout here or there as you try to work through all of this.

I do think that the Commission, having an open medical briefing once a year has been a major plus to this as far as the face-to-face is an important piece of it. And I don't think that we want to get ourselves into a letter writing campaign.

NEAL R. GROSS

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

As far as being busy goes, I know I have a dean who probably wouldn't like 36 days a year away with this type of thing. Having said that I think that all the people involved in this recognize that this is a professional commitment to the profession and to our direction with the regulatory agencies. I think we would find people still willing to serve, but it would probably be for shorter periods at a time at any point in time. But I do think that there are probably ways to enhance the current structure that probably accomplish the same type of advisory role that all our constituents would like to see happen.

And obviously, there's a Committee self-review that goes on here by mandate and I think that we can always reassess this thing and if we feel down the line that there's some unacceptable piece to where we currently stand, a letter-writing campaign at that point can probably always be done as well, but I guess I right now kind of tend towards an initial enhancement, Option 1.

CHAIR MALMUD: Thank you, Dr. Van Decker.

Other comments from members of the

Committee?

MEMBER GUIBERTEAU: Dr. Malmud, this is Mickey Guiberteau.

NEAL R. GROSS

CHAIR MALMUD: Yes.

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MEMBER GUIBERTEAU: As a new member of the Committee, although I've been here for some time now, although I can vote at this --

CHAIR MALMUD: Congratulations on your voting status.

MEMBER GUIBERTEAU: Thank you. this has been an excellent discussion. My concern here is that this process may go forward without any clear message from ACMUI about what our feelings may be regarding the staff recommendations that may go forward to the Commission. And being one who always careful what I wish for, since the Commission will make the decision, I think it might be best to take an opportunity to see how ACMUI feels at this moment in terms of the options that have been placed before us, understanding that in mу personal experience, although I'm aware of previous issues with ACMUI operations in the past from past members, as well from radiology nuclear medicine as and organizations, I can say truthfully over the last two years that it had seemed to work very well from my point of view. The staff has been very responsive. Our Chair and the Commission had excellent relations and communications. And my feeling is that unless

NEAL R. GROSS

1	there is a compelling reason to change, that perhaps
2	enhanced Option 1, in my mind, would be the better
3	option.
4	I also understand Dr. Langhorst's
5	questions and I believe that many of those can be
6	reframed in the context of the current reporting
7	system. So at this point I would like to move that
8	the tabled motion be removed from the table.
9	MEMBER LANGHORST: This is Sue Langhorst.
10	I second that.
11	CHAIR MALMUD: We have had a motion moved
12	and seconded. All in favor.
13	(Chorus of ayes.)
14	Any voting members opposed?
15	(No response.)
16	Any abstentions?
17	(No response.)
18	So there's a unanimous motion to take this
19	item off the table.
20	Next, is there a motion to present it?
21	MEMBER WELSH: Dr. Malmud, this is Dr.
22	Welsh.
23	CHAIR MALMUD: Dr. Welsh.
24	MEMBER WELSH: I was the one that
25	initially put forth the motion on January 5th. And
	NEAL D. CDOCC

1	would like to put the same motion forth again at this
2	point.
3	CHAIR MALMUD: Would you briefly just
4	describe your motion again for those who are on the
5	conference call?
6	MEMBER WELSH: The ACMUI should maintain
7	the current reporting structure with the proposed
8	enhancements.
9	CHAIR MALMUD: Thank you. And your motion
10	was seconded previously and therefore is open for
11	discussion again.
12	Any further comments with regard to the
13	motion from the members of the Committee?
14	MEMBER LANGHORST: Dr. Malmud, this is Sue
15	Langhorst.
16	CHAIR MALMUD: Yes.
17	MEMBER LANGHORST: Just a quick question
18	of my understanding of the enhanced means the request
19	for additional support, am I correct?
20	CHAIR MALMUD: You are correct.
21	MEMBER LANGHORST: Thank you.
22	MEMBER WELSH: Dr. Malmud, this is Dr.
23	Welsh.
24	CHAIR MALMUD: Dr. Welsh.
25	MEMBER WELSH: My comments are that I
	NEAL R. GROSS

concur with your sentiments in which would change our reporting structure that we could be the new stepchild in an organization that has bigger fish to fry with our new agendas such as new reactors.

Additionally, the very increased demand on ACMUI members in terms of time commitment is perhaps the reason I put forth the motion in the first place. It would become quite impractical for me and others such as Dr. Van Decker, among many others on this Committee, to comply with the demands of schedule. Thus, the motion was put forth, but I do still have the nagging suspicion that the current system is working not because it's such a perfect system, but because we have perfect individual people that we are working with now. And therefore, I will reiterate what I said before that perhaps this should be a question that gets readdressed on a periodic basis because I had my doubts that we'll always work as well as it is working today.

CHAIR MALMUD: So are you proposing a change in your motion?

MEMBER WELSH: Not a change in the motion, but perhaps if others agree, I would like to add that this same question be readdressed periodically, that we don't go for long periods of time with a system

NEAL R. GROSS

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

that might not be working as well as it is working at this moment. 2 3 CHAIR MALMUD: Would you wish your motion 4 to be as it is with an amendment indicating that we would like the Committee to reevaluate its decision and recommendation in a year? 6 MEMBER WELSH: That is what I would like 8 to put forth. CHAIR MALMUD: Would you like that to be 9 10 for the Committee to have this as an agenda item on an annual basis in the future, so that there's an 11 awareness that we always are looking for an alternate 12 13 reporting line if we feel that the current system for 14 one reason or another is not effective? 15 MEMBER WELSH: Yes. I think that would be 16 very valuable. 17 CHAIR MALMUD: Is there a second to that motion? 18 MEMBER GUIBERTEAU: 19 Second. Mickey Guiberteau. 20 21 CHAIR MALMUD: By Dr. Guiberteau. 22 further discussion of that motion by members of the Committee? If not, is this an appropriate time to ask 23 24 for comments from members of the public? I'm asking 25 this of NRC staff. Or shall we vote on the motion?

1	MR. FULLER: Dr. Malmud, it is at your
2	discretion. You can invite comment, invite folks from
3	the public to comment at any time.
4	CHAIR MALMUD: Before we vote or after we
5	vote or either?
6	MR. FULLER: It's either. It's up to you.
7	CHAIR MALMUD: How do members of the
8	Committee feel? Shall we vote first or ask for
9	comments from members of the public?
10	MEMBER GILLEY: I would like to hear the
11	comments from members of the public.
12	CHAIR MALMUD: Thank you. Debbie Gilley
13	ask that we give the courtesy of members of the public
14	speaking now and therefore I invite members of the
15	public to make comments if they wish. This is an
16	invitation for your participation.
17	Is there a member of the public who wishes
18	to make a statement?
19	MS. FAIROBENT: Dr. Malmud, it's Lynne
20	Fairobent with AAPM.
21	CHAIR MALMUD: Yes, Lynne.
22	MS. FAIROBENT: I just have a couple of, I
23	guess, comments based on the discussion and obviously
24	we have not had the opportunity to see the staff paper
25	that ACMUI has reviewed prior to this discussion. But

a couple of points, one, I don't know that you should automatically assume if you were to report to the Commissioners that ACMUI would have to meet at the frequency that ACRS or even in the past that the Advisory Committee on Nuclear Waste did. I think that those meeting frequencies reflect the workload that has been before both of those advisory committees. It may be, in fact, that your workload would only increase to perhaps three meetings a year or once per quarter. I think that that's something that you would have to weigh, depending on the activities before the Committee based on the medical policy issues.

Secondly, I was --

CHAIR MALMUD: Thank you for making that point. Is there a second item? Please go ahead.

MS. FAIROBENT: Secondly, I was also very interested in Dr. Fisher's comment in raising the question on rulemaking put forth by an organization other than FSME and Mr. Lewis' response in regards to those that are not directly related to medical policy. I think it is unclear in my opinion as to who would make the call that a rulemaking had an impact on medical policy.

The one in question in my mind is Part 37.

Part 37 definitely does have an impact in the medical

NEAL R. GROSS

application and use of radioactive material, but in that case that is not -- I do not believe it's an FSME 2 3 That is the regulation on increased controls 4 that you all spent a fair amount of time last week 5 discussing. MR. LEWIS: In fact, that is an FSME rule. 6 That rule is -- it's my division's rule. It's another 8 branch in my division. 9 MS. FAIROBENT: Okay. 10 CHAIR MALMUD: Thank you for clarifying 11 that. But who would make the 12 MS. FAIROBENT: 13 determination that another regulation would or would not have medical policy implications in deciding 14 whether it should be brought forward to ACMUI? 15 16 CHAIR MALMUD: I think that's a question for NRC staff. 17 MR. LEWIS: I believe that -- me. 18 19 MS. COCKERHAM: This is Ashley. That's how the procedure is currently written. 20 21 MR. LEWIS: Right. 22 MS. FAIROBENT: So just to clarify, that is really a staff-dependent decision. That just gets 23 24 back to the fact that right now the Committee I think 25 is quite frankly blessed with the staff support that

it has. That has not always been the case. It's not been the case for as long as I know ACMUI has been in operation.

In fact, I think it's probably the rarer percentage that ACMUI has had the operational support that it is currently in -- is enduring.

CHAIR MALMUD: This is Malmud. I would agree except for one word. You said "has". I would use the term "had" because currently we have been enjoying the opportunity.

The issue though is one which is of concern to all of us, namely, that is any regulations are passed which interfere with the availability of either diagnostic or therapeutic modalities, we would want -- we would feel a sense of urgency in commenting on that. That's exactly the kind of an issue that if we felt was not being dealt with effectively, we could communicate directly to a Commissioner, but with a quote drop-in end quote.

MR. LEWIS: Ashley, help me out. I thought that we have an annual briefing by DILR that goes over all the rules on their plate, medical policy and ones that may be indirectly medical policy. So is that not the way we do it right now? If it isn't, we can certainly change that.

NEAL R. GROSS

MS. COCKERHAM: do We have DILR presentation that's usually just on what the current 2 3 rulemaking is. Does that answer your -- or whatever 4 the current rulemakings are. 5 MALMUD: CHAIR Does that answer the concerns of both parties? 6 Rob? 8 MR. LEWIS: Yes, I think so. I'll talk --9 the right people aren't here for the rulemaking side, 10 so I'll talk to Josie Piccone and see if we're not doing that already, whether we can expand that. 11 Any other 12 CHAIR MALMUD: Thank you. 13 comments or questions from members of the public? 14 DR. LIETO: Yes. This is Ralph Lieto. 15 CHAIR MALMUD: Hello, Ralph. It's good to 16 hear your voice again. 17 DR. LIETO: Thank you. I appreciate that. I'll just introduce you. CHAIR MALMUD: 18 19 Ralph is a physicist who speaks as a former member of 20 the Committee, of the ACMUI. 21 DR. LIETO: Thank you. I have a number 22 of, I guess, questions or points and Lynne already 23 mentioned one of those. Not having access to the 24 report, it's obviously just picking up by 25 conversation what the pros and cons you're discussing and what the options are. So it makes it a little bit difficult to make some comments from the general public in that regard.

But I guess a question I have is since a lot of this, this issue basically arose, I'm going to say probably six or seven years ago and it's taken it this long to get to this point. Were any of the past ACMUI members that were involved or on the ACMUI during this time consulted in the sort of the pros and cons of reporting to the Commission in this report?

CHAIR MALMUD: The answer to your question is yes, at least one, and that is myself.

DR. LIETO: I don't consider you a previous member.

(Laughter.)

CHAIR MALMUD: You're correct. I was not a previous member. I was a member at that time and remain a member.

DR. LIETO: I think that would maybe be a little helpful in addressing some of these points. I think one issue that's been raised by Dr. Welsh is I think very true in that I think you do have now some very, very key members that have I think ameliorated the problems that existed before. And I think it also emphasizes the point that was made that as members

NEAL R. GROSS

change or I should say staff changes, we may not enjoy that -- those benefits that now exist.

So Ι think that is a problem with reporting at the level that currently the Committee is I think if you look at the hierarchal structure at. where the Committee reports relative Commission, you have about five layers or more of bureaucracy levels that are between the ACMUI and the Commissioners. So again, not knowing what the pros and cons and what the options were that are before the Committee right now, it's very difficult to make a recommendation as a member of the public, if any of these benefits have improved over the -- or present options that are an improvement over what the past has been.

One of the other things that I think might support reporting at a higher level, especially to the Commissioners, because of the increased scrutiny and awareness of radiation by the public and the concerns that have been raised about radiation exposure to members of the public, I think there's going to be continued awareness and scrutiny by outside federal agencies that are going to come to bear over the next couple of years. And reporting at a higher level, I think, would give the ACMUI some definite benefits in

NEAL R. GROSS

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

addressing some of these issues as they come before the NRC.

Another point, and I think it was a little misleading when they were talking about added budget and added time commitments. I think Lynne addressed it I think very appropriately and that you're only going to meet as often as there's business before the Committee. You're not going to just be meeting just for the sake of meeting and incur added costs and time commitments from that standpoint. But I think it needs to be pointed out that NRC is one of the very few agencies in the Federal Government that's feebased and as a licensee, I can tell you that fees have gone up absolutely astronomically over the last couple of years and that's because the NRC being fee-based is reimbursed from those and so their budget goes up, the fees go up.

So I think saying that there's going to be some kind of responsibility of answering to Congress to increase the budget because there might be an increased commitment of resources of the ACMUI, I think is a little misleading here.

One final point, I guess, regarding Dr. Welsh's request to make this an annual issue to be readdressed, in other words, keep the status quo, I

NEAL R. GROSS

2

3

4

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

think this is going to send a bad signal to the Commissioners because they're going to see that you're going to say hey, this is -- status quo is fine. What's going to change in a year that's going to make this want you to then go back and say no, we do want to report to the Commission? I think this is something that's been germinating for a very, very long time and I think you should consider making a decision on improving the reporting relationship of the Committee to the Commission.

CHAIR MALMUD: Thank you, Mr. Lieto. Does that complete your comment?

DR. LIETO: Yes. Thank you, sir.

Would respond to several of your points. I think the first one is that we have a direct means of addressing the Commissioners that we did not sense as available to us in the past. That deficiency may have been ours, not theirs. But we are encouraged to make a quote drop-in end quote when we feel the system is not working well or that there's an issue that needs their immediate attention.

The second issue is that the nature of the ACMUI members has changed over the years, the membership has changed. And of the course,

NEAL R. GROSS

2

3

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

Commissioners themselves have rotated, so that we are dealing with a different cast of characters, both with the Commission and with ourselves. The constant in this is probably more the NRC staff itself and it's working now. We agree that there's a risk that it may not in the future, but it's a potential risk rather than a real risk at the moment. Historically, at the time that you were on the Committee, it was perceived to be a real risk. And your point is well made that that could happen again.

Do you wish to make another comment, Ralph?

DR. LIETO: No. Well, I quess I would just say that if the Committee reporting relationship changed, that's going to be much more of constant than the change in staff and Committee membership. And I think that the issues that have been coming up in the past decade and I think issues that are going to be coming up in the near future, I think there's going to be an increased shall I say scrutiny or awareness regarding the use of radiation medicine. And Ι think in or at least my be recommendation would that the Committee be reporting at a higher level than currently exists.

Again, not knowing what the options and

NEAL R. GROSS

1

2

3

4

5

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

the pros and cons of what is being presented to the Committee right now to vote on makes it virtually impossible to make a specific recommendation on what's before you, but it is a little bit difficult to go forward, but I think that the one thing I think is at the status quo is really definitely not in the Committee's best interest.

CHAIR MALMUD: Thank you, Mr. Lieto. If I may, Mr. Lieto is a former member of the Committee and therefore we have heard an opinion from a former member of the Committee. And there was unhappiness which is what we have been dealing with.

In response to your question, basically there are two proposals being put forth by the ACMUI. One is to continue the current reporting line with enhancements to the staffing of ACMUI and NRC headquarters. The other option is to report in the same manner as the ACRS. That summarizes it.

Now the means by which we report under the ACRS would be something that would have to be worked out in the future. But those are the two options.

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

CHAIR MALMUD: Yes.

MEMBER LANGHORST: I would say that the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

motion that's on the table right now is one of this is how the Committee feels at this point in time, given this document and some of our discussions. But I go back to the question of what are the questions that should be asked and answered in this review and I think the Committee looks forward to hearing back from the Commission as to their sense of how things are working at this point in time. Thank you.

CHAIR MALMUD: Thank you, Dr. Langhorst. Will these be two separate issues then in your mind? One is the motion and the second is to present to the Commission these six questions that you've raised?

MEMBER LANGHORST: Well -- this is Sue Langhorst again. I feel like the Committee has been presented this document which obviously hasn't been presented to the public yet as it's in draft only. This is our sense at this point in time.

CHAIR MALMUD: Yes.

MEMBER LANGHORST: And I would hope that the questions that I suggested are part of this review that is being done by the staff and the Commission and ourselves.

CHAIR MALMUD: Would it be agreeable to you to vote first on the motion and then to have your six questions presented as a second motion as a

NEAL R. GROSS

1	question, overall question, to the NRC for a response
2	from them?
3	MEMBER LANGHORST: That's okay with me.
4	CHAIR MALMUD: Thank you. May we now
5	vote? Any further discussion?
6	MEMBER MATTMULLER: Dr. Malmud?
7	CHAIR MALMUD: Yes.
8	MEMBER MATTMULLER: This is Steve
9	Mattmuller.
10	CHAIR MALMUD: Yes.
11	MEMBER MATTMULLER: In regards to the
12	enhancements to the current structure, do those
13	enhancements include the ready adoption of the policy
14	and procedure 2-5? Because I think that's critical to
15	our Committee's actions and effectiveness that that
16	gets adopted as soon as possible.
17	CHAIR MALMUD: Is that part of your
18	motion, Dr. Welsh?
19	MEMBER WELSH: I don't think that it was.
20	CHAIR MALMUD: It was not a part of Dr.
21	Welsh's motion.
22	MEMBER MATTMULLER: I see. Well, then
23	maybe I should ask perhaps Rob. We have the draft for
24	2-5. Realistically how long would it take for that to
25	become effective?

MR. LEWIS: I believe that that procedure will become effective today. It's up front and they had one small question, Charlie Miller did yesterday which we resolved. And I expect he's going to sign it and it's immediately effected.

MEMBER MATTMULLER: Thank you.

CHAIR MALMUD: Thank you.

MS. FAIROBENT: Dr. Malmud, it's Lynne Fairobent.

CHAIR MALMUD: Yes, Lynne.

MS. FAIROBENT: Just one follow up based on Mr. Leito's comment.

CHAIR MALMUD: Yes.

MS. FAIROBENT: And your response -- right now, you have a Commission that is very open to your requesting drop-ins and to medically-related issues. That has not always been the case and I think that is also something else to perhaps keep in mind, that if the reporting status of the Committee were changed to interest of Commission, the personal the the Commissioners and the willingness to solicit input on medical issues does vary. But if the reporting structure was at the Commission, you would eliminate some of that variance that would be there.

CHAIR MALMUD: Your point is well made.

NEAL R. GROSS

2

3

5

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

Thank you. Any further discussion?

MEMBER WELSH: Dr. Welsh.

CHAIR MALMUD: Yes, Dr. Welsh.

MEMBER WELSH: Regarding some of Ralph's points that I think are very important to keep in the back of our minds, there is this new public perception and perhaps political pressure thanks to the recent medical radiation mishaps that the ACMUI -- there's a perception that the ACMUI might not be as in touch with the Commissioners as it truly is. And I wonder if this is perhaps part of the reason why the Commission put forth this charge to us in the first place, raised this question.

So having direct reporting to the Commissioners would solve that problem and it would also solve the problem that is raised as one of the cons for Option 1 which is that there's a perception of diminished status of the ACMUI. Having said this, my motion is in favor of Option 2. I'm sorry, is in favor of maintaining the current reporting scheme.

But is there any way that we can assuage the concerns of the public, the political pressure and the perception of diminished status of the ACMUI at this time as well? How can we improve the ACMUI's status or at least the perception of the status and

NEAL R. GROSS

convince the public, convince anyone who is putting pressure on the Commissioners that the ACMUI does have very good access to the Commission and that the proposed reporting structure is not in any way going to impede that?

This is a question that I don't know has a direct answer, but I think it's worthy of something.

CHAIR MALMUD: I can answer your question with a question and that is do you feel, as a member of the ACMUI, that we have adequate access to the Commissioners currently?

MEMBER WELSH: Well, I think that's a very good question and the answer today is yes, but hearing Ralph Lieto on the phone reminded me that a few years back the answer might not have been a definitive yes. And as Ralph and others have pointed out, next year or whenever the Commissioners change, the answer might no longer be a resounding yes as it is today.

So the answer today is yes. And I'm not one hundred percent sure that it's because of our reporting scheme or because of the individuals. I would love to ensure that the reporting scheme is what ensures excellent access to the Commissioners rather than our excellent access being dependent on high quality individual people.

NEAL R. GROSS

CHAIR MALMUD: Thank you. Are you still supporting your initial motion which is on the table? 2 3 MEMBER WELSH: Ι suppose I'm still supporting the motion and perhaps emphasizing that 4 although there is reason for not bringing this up on an annual basis as Ralph has pointed out, that I feel 6 strongly that we must because if we go forth with the 8 vote and it's in favor of the status quo, I don't want 9 to be boxed in to this for years to come if it turns 10 out that the reason why it's working well today is because of Ashley, Chris, Rob, and Charlie and the 11 Commissioners in existence today. 12 13 If things change next year and we have 14 different individual people, and we find that the 15 system is not working as well, I would like to bring 16 this back on the table. MR. LEWIS: Dr. Malmud? 17 CHAIR MALMUD: Yes. 18 19 MR. LEWIS: I think --20 CHAIR MALMUD: Who is speaking? 21 MR. LEWIS: It's Rob Lewis. 22 CHAIR MALMUD: Yes. 23 MR. LEWIS: If there was a concern that 24 there's a perception of waffling, if you will, in 25 saying that the Committee would revisit it in one

year, the Committee had two motions. There was a motion to support the current structure. And I think there was a separate motion to revisit it in a year. And the fact of the Committee revisiting in a year wouldn't necessarily have to be provided to the Commission. I mean the Committee could still revisit it in a year.

If the Committee preferred, we would provide it to the Commission. I don't care either way, but if there's a concern there that it is possible to separate those two things.

CHAIR MALMUD: Yes, I believe that they were separated, but that may be a misunderstanding on my part. It would be my recommendation that if we go ahead with recommendation number one, that we, within the Committee, recommend that this be an annual issue to be raised within the ACMUI so that it could be addressed immediately in the event that it became an issue of concern in the future.

In other words, that it be an item that we revisit each year internally, not necessarily to bring it before the Commissioners, but to discuss our own satisfaction with the operation in which case if we were dissatisfied, we would bring it before the Commissioners.

NEAL R. GROSS

Is there further discussion of the item on the table, the motion on the table? 2 If not, all in favor of the motion which 3 4 is to recommend Option 1 with enhancements to the 5 Advisory Committee. (Chorus of ayes.) Any voting members against? 8 (No response.) 9 Any abstentions? 10 (No response.) The motion carries unanimously for Option 11 1 with the statement that it is with the enhancement 12 to the staffing of the Committee. 13 14 MS. COCKERHAM: Dr. Malmud, this is I had a quick question. 15 Ashley. 16 CHAIR MALMUD: Yes. 17 MS. COCKERHAM: Just based on this discussion and what I had heard at the last meeting, I 18 19 had provided a statement in the background document 20 and I just want to make sure this reflects exactly what the motion is. The NRC staff should maintain the 21 22 reporting structure for the ACMUI current 23 enhancements in communication as described in FSME 24 policy and procedure 2-5 and increased support staff. 25 CHAIR MALMUD: That's correct. Now there

was a suggestion made -- does anyone wish to formalize the suggestion that this issue be considered an item on the agenda annually to reevaluate the ACMUI's satisfaction with the reporting?

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

CHAIR MALMUD: Yes.

MEMBER LANGHORST: I have a question.

CHAIR MALMUD: Yes.

MEMBER LANGHORST: Before we get to that.

It's not clear to me that we will see the final document that NRC staff puts forward. Am I correct in that assumption?

CHAIR MALMUD: I'll address your question to NRC staff.

MR. LEWIS: I will -- I can give the Committee the document as I get it for concurrence. After I concur, there's still -- Ralph mentioned five levels. It's not five, but there's still two or three that would need to concur and may edit it, but I can commit to providing it to the Committee. It will not be public, but at least to the Committee members at the time that I get it to make sure that all the discussions today were accurately captured in the report. Because I'm very interested to ensure that

NEAL R. GROSS

the Commission gets the report that accurately captures the staff view and the ACMUI view. 2 CHAIR MALMUD: 3 Thank you. Does that 4 address your concerns? 5 MEMBER LANGHORST: Well, I would say -this is Sue Langhorst again. I would just say that 6 again, I think the Committee is very interested in 8 hearing what goes on above Rob's level and feedback we 9 get from the Commission, maybe not necessarily the 10 report, but we certainly -- I mean I feel we're not done with this issue today and then a year from now 11 we'll look at it again. 12 I would say this is a dialogue right now, 13 14 if this is how we feel at this point in time and when 15 the decision comes, we probably will be looking at it 16 on an annual or periodic basis. So that's my opinion. 17 MR. LEWIS: I would just offer, too, that at above my level there's a substantive change, if you 18 19 use discretion on trust me to quys can 20 substantive means, I will agree -- I'll get it back 21 before you. 22 MEMBER LANGHORST: I think that would be great. Thank you, Rob. 23 24 CHAIR MALMUD: Are there any other items 25 for discussion?

1	MEMBER WELSH: Dr. Malmud?
2	CHAIR MALMUD: Who is speaking?
3	MEMBER WELSH: This is Dr. Welsh. I was
4	going to put forth a motion.
5	CHAIR MALMUD: Please do.
6	MEMBER WELSH: I would volunteer the
7	motion that this question of reporting of the ACMUI be
8	brought up on an annual basis.
9	CHAIR MALMUD: Is there a second to the
10	motion that it be an agenda item annually within the
11	ACMUI?
12	MEMBER ZANZONICO: Seconded. This is Pat
13	Zanzonico.
14	CHAIR MALMUD: Thank you. Any discussion
15	of the motion? All in favor?
16	(Chorus of ayes.)
17	Any opposed?
18	(No response.)
19	Any abstentions?
20	(No response.)
21	Thank you. The motion is passed that this
22	be an item within the ACMUI for annual review.
23	Now I didn't mean to ignore Dr.
24	Langhorst's six points. And may we ask that we could
25	get some clarification from NRC with regard to the six

questions that were raised by Dr. Langhorst.

MR. LEWIS: I am confident that in the paper that we draft we can probably build it around these points with probably one exception. The paper, we're not asked at this time to give advice on how other organizations or the public can comment to the Commission. I think we have to limit it to the Committee.

Now how other organizations may provide their views to the Committee I think we can work in something, but in terms of outside organizations giving comments on rules, for example, to the Commission, this paper won't get into that.

CHAIR MALMUD: Thank you for that clarification.

Dr. Langhorst, are you satisfied with that?

MEMBER LANGHORST: Yes, and I would respond -- this is Sue Langhorst -- to Rob that it's not how the public or medical community and so on provide their interactions, it's how the organization of the ACMUI impacts that process. So that was my meaning in that. And I'll be glad to forward these questions to Ashley.

CHAIR MALMUD: Thank you. And thank you

NEAL R. GROSS

for the clarification.

2

3

6

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

MEMBER LANGHORST: Dr. Malmud, I would mention that these were just questions that I raise. I don't know if they are the appropriate questions to be asked, but they are the thought process that I was going through as I was considering this review.

CHAIR MALMUD: Thank you. I think they were clear and rather thorough. Unless other members of the Committee have comments, we will ask for responses for those questions.

I would like to make another comment and that is with respect to the other option, Option 2. There should be -- as Chairman, I will give assurance that if we perceive as a Committee that things are not working well under Option 1 with whatever changes are made, we will definitely revisit this promptly. And make certain that the Commissioners are aware of our concerns should they arise.

Is there a motion for adjournment of today's meeting, as all of the business is carried out?

MEMBER GUIBERTEAU: So moved.

CHAIR MALMUD: A second?

MEMBER GILLEY: Second. Debbie Gilley.

CHAIR MALMUD: Thank you, and thank the

NEAL R. GROSS

COURT REPORTERS AND TRANSCRIBERS 1323 RHODE ISLAND AVE., N.W. WASHINGTON, D.C. 20005-3701

75 members of the public for having joined us and thank you, of course, members of the ACMUI and of the Commission. Good-bye. (Whereupon, at 2:47 p.m., the teleconference was concluded.) 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23

NEAL R. GROSS