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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

SPRING 2019 MEETING

+ + + + +

THURSDAY,

APRIL 4, 2019

+ + + + +

The meeting was convened in Room 1-C03/1-C05, Three White Flint North, 11601 Landsdown Street, Rockville, Maryland, at 8:30 a.m., Christopher J. Palestro, ACMUI Chairman, presiding.

MEMBERS PRESENT:

CHRISTOPHER J. PALESTRO, M.D., Chairman

DARLENE F. METTER, M.D., Vice Chairman

VASKEN DILSIZIAN, M.D., Member

RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

MELISSA MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

ARTHUR SCHLEIPMAN, Ph.D., Member

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MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

LAURA M. WEIL, Member

NON-VOTING MEMBER PRESENT:

HARVEY B. WOLKOV, M.D.

NRC STAFF PRESENT:

CHRIS EINBERG, NMSS/MSST/MSEB, Branch Chief,
Designated Federal Official

MARYANN AYOADE, NMSS/MSST/MSEB/MRST

LAURA CENDER, R-III/DNMS/MLB

SAID DIABES-FIGUEROA, NMSS/MSST/MSEB/MRST

LISA DIMMICK, NMSS/MSST/MSEB/MRST, Team Leader

SARA FORSTER, R-III/DNMSS/MLB

CASSANDRA FRAZIER, R-III/DNMS/MLB

ROBERT GALLAGHAR, R-I/DNMS/MLAB

SOPHIE HOLIDAY, NMSS/MSST/MSEB

ESTHER HOUSEMAN, OGC/GCRPS/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSST/MSEB/MRST

IAN IRVIN, OGC/GCRPS/RMR

KELLEE JAMERSON, NMSS/MSST/MSEB, ACMUI
Coordinator

ERIN KENNEDY, R-III/DNMS/MLB

PENNY LANZISERA, R-I/DNMS/MLAB

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SCOTT MOORE, NMSS, Deputy Director
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DENNIS O'DOWD, R-III/DNMS/MIB
PATRICIA PELKE, R-III/DNMS/MLB
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KATIE TAPP, Ph.D., NMSS/MSST/MSEB
KEVIN WILLIAMS, NMSS/MSST
IRENE WU, NMSS/MSST/MSEB

MEMBERS OF THE PUBLIC:

DANNY ALLEN, NuTech, Inc.
ERIC ANDERSEN, Dana-Farber Cancer Institute
KENDALL BERRY, Fox Chase Cancer Center
BETTE BLANKENSHIP, American Association of
Physicists in Medicine (AAPM)
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SHERRIE FLAHERTY, Minnesota Radioactive Material
Unit

MICHAEL FULLER, Virginia Office of Radiological
Health

MATTHEW HADDEN, Virginia Office of Radiological
Health

MATTHEW HALL, NorthShore University Health
System

STANLEY HAMPTON, Eli Lilly

PAUL KANABROCKI, Virginia Office of Radiological
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JEFF MASON, Virginia Office of Radiological
Health

STEVE MATTMULLER, Kettering Health

ANDREW MCKUSICK, *Unknown*

ASHLEY MISHOE, University of California, San
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P R O C E E D I N G S

(8:31 a.m.)

CHAIRMAN PALESTRO: All right, good morning. We're getting ready to start Day 2 of the ACMUI Spring 2019 meeting. And the first session on today's agenda is the ACMUI reporting structure and it will be reported by Ms. Kellee Jamerson.

MS. JAMERSON: I will be giving the annual presentation on the committee's reporting structure.

So our outline for today includes the current reporting structure. This presentation will serve as your annual review. We will discuss how often we conduct our meetings and then open it up for a discussion.

This chart shows the organizational structure within the NRC from the Division of Materials Safety, Security, State, and Tribal Programs, up to the Commission.

The ACMUI reports directly to Ms. Andrea Kock, Director of the Division of Materials Safety, Security, State and Tribal Programs.

My branch, the Medical Safety and Events Assessment Branch also reports to Ms. Kock.

While the ACMUI does not report to the Medical Safety and Events Assessment Branch or MSEB,

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1 MSEB is responsible for supporting the day-to-day
2 activities of the committee.

3 The dotted lines, as you see on the left,
4 indicate that while you may report to Ms. Kock or Kevin
5 Williams, our Deputy Division Director, this does not
6 preclude you from communicating or interacting with
7 the Director of our office, the Office of Nuclear
8 Material Safety and Safeguards or our Executive
9 Director of Operations, or to the Commission.

10 In September 2012, as indicated on the old
11 business chart, the ACMUI recommended to have an annual
12 review of the reporting structure open indefinitely.

13 In May 2014, the Bylaws Subcommittee at that time
14 presented the committee with the option to continue
15 reporting to NMSS or directly to the Commission.

16 The subcommittee report stated that the
17 working relationship between the NRC and the ACMUI
18 remains excellent. The reporting structure, through
19 NRC staff, continues to function effectively and the
20 associated logistical overhead associated with direct
21 reporting to the Commission did not and does not now
22 justify any change in the ACMUI's reporting structure.

23 This presentation marks the ninth review
24 of the reporting structure.

25 Currently, the ACMUI holds two meetings

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1 at NRC Headquarters each year. The spring meeting
2 takes place in either March or April and the fall meeting
3 occurs in September or October.

4 The ACMUI also has approximately two to
5 three teleconferences per year, as needed. We have
6 already conducted one teleconference on February 26th
7 and we will likely have two more this summer to receive
8 the committee's comments on the staff's draft
9 commission paper related to the training and experience
10 requirements and the draft revisions to Regulatory
11 Guide 8.39.

12 As you can see, the number of
13 teleconferences varies, depending on the needs of the
14 committee, as well as the needs of the staff and the
15 Commission.

16 At this point, I would like to open it up
17 for discussion to the committee and, for your
18 consideration, these questions for you to discuss.

19 Do you still agree with the current
20 reporting structure where the ACMUI reports to the MSST
21 management or would you rather report directly to the
22 Commission?

23 Are you satisfied with the frequency of
24 the meetings; that is, two in-person meetings here at
25 NRC Headquarters, with as-needed teleconferences?

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1 And lastly, are there any other changes
2 that you would like to see?

3 I will turn it over to Dr. Palestro.

4 CHAIRMAN PALESTRO: Dr. Metter?

5 VICE CHAIRMAN METTER: Thank you, Kellee.

6 Do you mind going back to that chart? You
7 have the directors and I know you probably know who
8 they are but can you give us their names so we know
9 -- can identify a name with the position?

10 MS. JAMERSON: Sure. John Lubinski is the
11 Director of NMSS, whom you met yesterday.

12 The Director of MSST is Andrea Kock. She
13 could not attend. Our Deputy Director is here, Kevin
14 Williams.

15 Our Executive Director of Operations is
16 Margaret Doane.

17 VICE CHAIRMAN METTER: Okay, thank you.

18 CHAIRMAN PALESTRO: Other
19 questions/comments?

20 I have a question regarding the reporting
21 structure. The way it is designed, we report up through
22 various levels. What would be the advantages or
23 disadvantages of changing that reporting structure?
24 Because I certainly have no idea.

25 MS. HOLIDAY: Okay, so this is Sophie

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1 Holiday, for those listening on the webinar.

2 So currently we have three Federal Advisory
3 Committees or FACA Committees here at the NRC. The
4 one that everyone is most familiar with, aside from
5 our committee here, is ACRS, which is the Advisory
6 Committee for Reactor Safeguards. And that is the only
7 FACA committee here at NRC that reports directly to
8 the Commission.

9 So because they report directly to the
10 Commission, they have their own office, if you will,
11 a dedicated staff that helps them because they generate
12 a lot of letter reports, as I understand it. They meet
13 here at headquarters at least ten times a year for
14 in-person meetings and also subcommittee meetings
15 in-between or also during those ten meeting times a
16 year.

17 Honestly, reporting directly to the
18 Commission versus reporting through the division,
19 through our division, MSST, is not necessarily very
20 different in terms of if you feel the ACMUI wants to
21 have access to the Commission, the dotted lines from
22 ACMUI to the Director of NMSS, to EDO, or to the
23 Commission simply means that we have an open door
24 policy.

25 Maybe a couple of the members on the

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1 committee may remember at one time our previous
2 chairman, I believe it was Dr. Thomadsen, scheduled
3 drop-in meetings with the Commission, particularly,
4 he held them the day before the ACMUI meeting when it
5 was convenient because he was in town at that time.
6 At any other time, any member here on the ACMUI can
7 request to have a meeting with any of our commissioners,
8 or the EDO, or any of our levels of management.

9 In terms of the disadvantages, I think one
10 of the reasons, as I recall from the paper that Kellee
11 referenced before, the reason that the committee had
12 previously stated that they wanted to retain the current
13 reporting structure, that is, to report through our
14 division and our office, is that it would be less
15 frequent meetings, not to say that you would not be
16 as visible to the Commission but you would not be as
17 demanded of, if that makes sense.

18 Because a lot of our rules and our
19 regulations here at the NRC are very much so centered
20 around nuclear reactors, that is why that particular
21 FACA Committee meets as frequently as they do, produces
22 as many reports as they do. Their reports do go
23 straight to the Commission; whereas, for the committee,
24 any subcommittee report that you submit and it ties
25 into any policy changes that the NRC staff is pursuing,

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1 we append your unfettered comments, which is your report
2 to our SECY papers, to our memorandums, to our
3 Commissioner Assistant notes, so that they are able
4 to hear verbatim what the committee has said.

5 Hopefully, that answered your question.

6 CHAIRMAN PALESTRO: Yes, it does. Thank
7 you.

8 MS. HOLIDAY: Thank you.

9 CHAIRMAN PALESTRO: Any other questions
10 or comments? Ms. Weil.

11 MEMBER WEIL: As the historian, I guess,
12 on this committee, when I first came on there was some
13 question about why an annual review. Why can't we just
14 settle on how we function? And the reason I was given,
15 and this occurred before my time, before Kellee, before
16 Sophie, before Ashley, there was some dissatisfaction
17 on the ACMUI with the staff support that we had.

18 And so there was a decision made to annually
19 review whether we are content with the support that
20 the committee is given and whether we want to continue
21 in our current organizational structure.

22 I just thought I would offer that
23 perspective.

24 CHAIRMAN PALESTRO: Thank you.

25 Any other comments or questions?

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1 Is there a general consensus that we are
2 content with the structure, recognizing that many of
3 you are new on the committee and haven't had a lot of
4 experience with it?

5 Dr. Ennis.

6 MEMBER ENNIS: Just my personal opinion,
7 I am content. Actually, overall, content in this part
8 of my life.

9 (Laughter.)

10 MEMBER ENNIS: You know over the years that
11 I have been on, the NRC staff has been fabulous.

12 I do have, as I expressed a little bit
13 yesterday, though, a little bit of a concern about
14 whether they have enough support. I don't know if,
15 personally, I am at a point where I feel like we need
16 to do something about it because there have been some
17 additions with Kellee and a new position. So
18 personally, I may be willing to kind of give it another
19 six months to a year. But even with that issue, I don't
20 think that is so much about structure but it may be
21 about whether we need to have a meeting directly with
22 someone higher up on the chain.

23 CHAIRMAN PALESTRO: Zoubir.

24 MEMBER OUHIB: I would just like to echo
25 what Dr. Ennis just said. I really believe that there

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1 is still need for more support for the staff in order
2 for the ACMUI to actually accomplish what we want to
3 accomplish. There are other things that we probably
4 could tackle but I think knowing that the staffing is
5 probably not ideal, we tend to back up rather than try
6 to push.

7 CHAIRMAN PALESTRO: Thank you.

8 Any other comments?

9 Mr. Einberg?

10 MR. EINBERG: This is Chris Einberg.

11 In regards to the staff support, in the
12 past year or so, there have been challenges with the
13 backfilling for some people that were out. I think
14 we are righting the ship in that regard. And so we
15 are putting priority and trying to -- we are going to
16 put an additional priority on closing these open items.

17 We heard you yesterday and we will make that a priority
18 to close some of these open items.

19 And so if there is a need for additional
20 staff support, management here does support getting
21 additional resources. We have the flexibility to try
22 to bring on people on rotations and details to help
23 close some of these action items. So we will work those
24 issues to try to close those action items and get the
25 support you need.

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1 Other than the open items, is there
2 anything else that you feel that there is additional
3 support needed?

4 CHAIRMAN PALESTRO: Dr. Ennis?

5 MEMBER ENNIS: I don't have a specific
6 thing but, as Mr. Ouhib just mentioned, we do, or at
7 least I feel like we function a little bit with a cloud
8 over our heads -- well, don't ask for too much or don't
9 try and do too much because the staff can't do that.
10 That's not really an ideal way for ACMUI to function.

11 MR. EINBERG: I'm not sure I understood
12 the comment. Perhaps you can rephrase it.

13 The staff is asking you not to do too much?

14 MEMBER ENNIS: No, it's just that we get
15 a feeling. Like because things take a long time and
16 occasionally, there will be comments like within our
17 -- we will tackle that within our resources.

18 Now of course, we understand there is a
19 budget, and a federal deficit, and all of that but it
20 feels a little bit like, in such a big organization,
21 to have such limited resources isn't a good balance.

22 And it feels just like it is something that we have
23 to always be aware of; you can only do a little bit.

24 MR. EINBERG: Okay.

25 MR. WILLIAMS: So also, if I may, this is

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1 Kevin Williams, the Deputy Director.

2 So those types of activities, and I know
3 I can speak on behalf of Andrea, she wants to be aware
4 of those types of activities. We are constantly
5 looking at our workload, and analyzing it to see how
6 best to support all of the things that we are doing.

7 I certainly wouldn't want you to feel as
8 though there is a cloud or we are limited in terms of
9 what we can do. So, we would like you to bring those
10 types of things up to us. You can work through Kellee,
11 and Chris, and so forth but we will address what we
12 can but we can't necessarily address what we don't know.

13 And so I appreciate your candor and I would
14 ask that you continue to push and let us know where
15 the challenges are because we will identify those.

16 I think yesterday one of the things we
17 talked about was the plans and the activities that we
18 have committed to. Chris and I talked offline and that
19 was one of the things that we said we wanted to make
20 sure we have a plan with a milestone and schedule.
21 So that is one thing that we know that is tangible and
22 that we can actually address.

23 So I would look forward to continue
24 engaging and letting us know where there are areas that
25 we can enhance the program.

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1 MEMBER ENNIS: That's great. I
2 appreciate it.

3 Just to be clear, the individuals with whom
4 we work are fabulous. It is not meant at all as a
5 criticism of the current staff that we have.

6 MR. WILLIAMS: No, I know that.

7 CHAIRMAN PALESTRO: Dr. Metter.

8 VICE CHAIRMAN METTER: Thank you, Kellee.

9 And this may be a very minute question but
10 you know when we talk to NRC staff and then you say
11 you have to clear it with management, who is that?
12 Oh, okay. Thank you, Kevin. Okay.

13 CHAIRMAN PALESTRO: Zoubir.

14 MEMBER OUHIB: Just to echo Dr. Ennis again
15 is that I just want to make sure this is clear. This
16 is not a wave that is coming from the staff, in all
17 honesty. Because again, they are great, very
18 accommodating and will do whatever they can. It is
19 just more like us, at least from my point of view, us
20 looking at the whole program and try to see well, yes,
21 we could look into this, we could look into this but
22 can we really do it? Listen to what they are dealing
23 with and what they have to meet, and so on and so forth.

24 So we tend to well, let's just wait a little bit and
25 then maybe we can address this or we can address that.

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1 I mean ideas come and go and we are like
2 maybe next year, whatever. So I just want to make sure
3 it is not coming from them. It is us looking at it.

4 MR. WILLIAMS: Yes, so how I would respond
5 to that is I want to go on the record as saying I think
6 Sophie and Kellee do a great job. They are amazing
7 and they work diligently to make sure that this program
8 runs at a high-functioning level.

9 So I would want to reiterate is the fact
10 that the whole purpose of this is to take that critical
11 look at the program, the processes, and to say hey,
12 is there something that we can do better. We wouldn't
13 want you to feel as though you were limited. So there
14 are things that you are thinking about. Let's talk
15 about those things because in talking through them,
16 we can develop plans. We can look at it and see if
17 there is a way to do it.

18 We don't necessarily have to move at a
19 snail's pace but if you are bringing those issues up
20 to us, we are aware of what they are and we can take
21 some sort of action.

22 CHAIRMAN PALESTRO: Any other comments or
23 questions from the committee? Mr. Fuller.

24 MR. FULLER: Yes, this is Mike Fuller and
25 I am the Director of the Virginia Radioactive Materials

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1 Program but I have some experience.

2 So again, to bring a little bit more of
3 an historical perspective, I guess, one thing that
4 hasn't been mentioned and I know everybody knows this,
5 but just so that the new folks on the ACMUI are also
6 aware, there is another big difference between the ACRS
7 and the ACMUI.

8 The ACRS reports directly to the
9 Commission, yes, and they have certain areas of
10 expertise. Each of the members are you know highly
11 specialized in what they do. But the NRC staff has,
12 possesses all of those skills, all of that knowledge,
13 and that experience, and so forth, the same sort of
14 specialists. So it works for the ACRS to report
15 directly to the Commission because the staff has the
16 exact same expertise, or at least very similar
17 expertise.

18 What is different and one of the reasons
19 why the ACMUI reports to staff is because this committee
20 comprises and has certain technical, medical, clinical
21 expertise that the staff does not have. So this
22 committee advises the staff because the staff does not
23 have what you have as far as experience and expertise.

24 So that is another reason why this
25 committee reports and supports the staff, as opposed

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1 to the Commission, because if you reported directly
2 to the Commission, the Commission would not have another
3 -- so with the ACRS, the Commission can hear from the
4 Advisory Committee can also hear from staff and get
5 maybe two perspectives, or maybe a different nuanced
6 perspective. Whereas, if you reported directly to the
7 Commission, the staff has nothing to offer.

8 So anyway, I just thought I would add that.

9 Like I said, I think that is sort of in the back of
10 everybody's mind but it just didn't come up in this
11 discussion and for the benefit of the newer members
12 on the ACMUI.

13 So thank you.

14 CHAIRMAN PALESTRO: Thank you.

15 Any other comments or questions?

16 One item that I think comes up periodically
17 is the number of face-to-face meetings per year. So
18 I would ask if the committee has any thoughts on that.

19 As you all know, we meet twice a year; fall
20 and spring. And the discussion has come up
21 periodically as to whether or not a third or fourth
22 face-to-face meeting could potentially be useful or
23 necessary. So I am just putting that out for a
24 discussion and comment.

25 Dr. Ennis.

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1 MEMBER ENNIS: It looks like there are so
2 many new members who can't really offer an opinion on
3 that so, I will speak up that I think it is an appropriate
4 balance. It feels to me twice a year is good -- is
5 the right amount.

6 CHAIRMAN PALESTRO: Yes, this question
7 comes up periodically at these annual reviews and it
8 has generally been a consistent response that while
9 an additional face-to-face meeting or two might be
10 desirable, the logistics involved and so forth far
11 outweigh any benefits. And that at least at the present
12 time, and again, we have the opportunity to review it
13 annually.

14 The two face-to-face meetings,
15 supplemented with a sufficient number of telephone
16 conferences during the year are sufficient to complete
17 our business.

18 Any other comments? Zoubir.

19 MEMBER OUHIB: Yes, I think biannual is
20 probably sufficient. However, with the emerging
21 technology and things that we are all going to be dealing
22 with in the very near future, perhaps to sort of not
23 necessarily say okay, let's do it three times or
24 something like that, but be flexible and have the
25 ability to add another face-to-face meeting to sort

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1 of deal with urgent matters that will come along.

2 CHAIRMAN PALESTRO: All right, thank you
3 for that.

4 Maryann.

5 MS. AYOADE: Yes, Maryann, NRC member.

6 I just wanted to add that we do have
7 opportunities where if the ACMUI members feel that they
8 need additional face-to-face, we can try to accommodate
9 that.

10 For example, last year with the T&E
11 Subcommittee, Dr. Metter asked for a face-to-face
12 working day with the subcommittee a day before the
13 meeting. And we were able to accommodate that. And
14 that worked with people's schedules because they didn't
15 have to plan a separate visit outside of the two annual
16 or the two times you guys come in in the year.

17 And I don't know, historically, if, Sophie,
18 this has been done before but we were able to accommodate
19 that. So that might be something that some of the
20 members may want to consider if they think a
21 face-to-face meeting would benefit their subcommittees
22 in moving forward.

23 MS. HOLIDAY: Hi, Maryann. Thank you for
24 that input.

25 And Maryann is quite correct. We did do

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1 that last year for the T&E Subcommittee. For the time
2 that I have been with the committee, has been roughly,
3 oh, gosh, nine years, I can only remember maybe one
4 or two other instances where we brought members in a
5 day before the meeting. And that was really more so
6 to do the Commission dry run because, at that time,
7 the Commission meeting was on Day 1 of the ACMUI meeting
8 versus Day 2.

9 That being said, you know just like Maryann
10 said, if this is something that the committee desires,
11 subject to budget availability because travel does cost
12 quite a bit of money and our members are scattered across
13 the country, you know we would do our best to support
14 you in those efforts.

15 With respect to what Mr. Ouhib said
16 regarding emerging medical technologies and I believe
17 the word you used was urgent, I personally find that
18 with urgent matters, an ad hoc teleconference is a
19 better approach in terms of it allows you a little bit
20 more flexibility, members are able to set aside two
21 -- you know one to three hours. I think our longest
22 teleconference has been three hours for a given topic
23 or two topics.

24 The reason that we have these in-person
25 meetings twice a year is because it covers several

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1 different topics. So unless, for example, the emerging
2 medical technologies, if that had evolved into numerous
3 agenda topics where it could cover a day or two, I think
4 NRC would be very supportive of that.

5 But like we said, we are flexible. It
6 hasn't happened yet but if it does come to that point,
7 I don't see an objection.

8 I see nods from the management.

9 CHAIRMAN PALESTRO: Any other comments or
10 questions? Dr. Dilsizian.

11 MEMBER DILSIZIAN: Thank you.

12 I guess my observation over the last three
13 or four years now, is that I don't see any issue of
14 ACMUI coming up with an agenda and recommendations.
15 The reason I think we don't need more than two is because
16 a lot of our recommendations don't actually become
17 reality for several years.

18 So I don't understand what the urgency
19 would be because I feel like I have been on this
20 committee, this is my fifth year, a lot of things that
21 we have discussed, that we have proposed, or
22 recommended, we are still very active and nothing is
23 happening. So to me, the urgency of doing more meetings
24 would be if those actually become actionable items.

25 So we can talk all we want to. We can

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1 present all these nice ideas but I think that there
2 doesn't seem to be urgency from the NRC. So we can
3 just only advise but it doesn't seem to be moving
4 forward.

5 So that would be my comment.

6 CHAIRMAN PALESTRO: Thank you. I'm
7 inclined to agree with you. Certainly at the moment,
8 it is hard to identify something that is urgent and
9 there is no way to know about urgency looking into the
10 future. On the other hand, I think it is nice to know
11 or to have the sense that if we do feel there is an
12 urgent need for a meeting, that we have the support
13 of staff and management, in the event that we so
14 desire.

15 Any other comments or questions?

16 MS. HOLIDAY: Dr. Palestro, if I could just
17 quickly respond, and I'm sorry if I am going to, perhaps,
18 steal your thunder, Chris.

19 But with respect to the timeliness of
20 responding to the actionable items, if you'll notice,
21 a lot of the items we close, we closed several charts
22 in the fall meeting because they were all tied to the
23 rulemaking effort. And as a federal agency, we have
24 to follow our regulatory process in terms of rulemaking
25 efforts. That means that we have to engage members

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1 of the public. We have to satisfy all the steps, and
2 there is a flow chart, all of the steps that you have
3 to do for a rulemaking.

4 So for rulemakings, you know we always joke
5 about how it took ten years to push this rule out and
6 ideally, you know we would like things to hit the street
7 within six months. But the reality of it is in order
8 to give a topic, especially one that can be as sensitive
9 and as controversial as medical, that rulemaking got
10 extended and there were several questions. At one
11 point, the ACMUI members participated in specifically
12 a Commission meeting regarding a permanent implant
13 brachytherapy, if I recall. Correct? I see a couple
14 of nods in the audience.

15 So because of things like that, that is
16 why some of the items take us longer to close and it
17 is not because we don't want to take action or that
18 we aren't taking action. Our action may be to -- we
19 are addressing it but we still have to follow that
20 regulatory process.

21 Whereas, other things, actionable items,
22 for example, some subcommittee reports related to
23 licensing guidance. As you guys know, 35.1000
24 licensing is a much more nimble, quicker effort than
25 a rulemaking. As of lately, we have been able to push

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1 out 35.1000 licensing guidance within about a year time
2 frame, which is significantly faster than a rulemaking.

3 With regard to rulemaking, there is also
4 another process called a direct final rule, which still
5 has to go through the regulatory process but it is not
6 as -- it doesn't have as many steps as the Part 35
7 rulemaking that we just went through.

8 So if you guys recall, a couple of years
9 ago when Steve Mattmuller was on the committee, he
10 talked about the decommissioning funding plan and how
11 the subcommittee and the committee, ultimately,
12 endorsed the report that said we recommend a direct
13 final rule. And direct final rules are for things where
14 we think that there will be less, or very minimal, or
15 no controversy. But if we get into that process and
16 there ends up being a lot of controversy, then it kicks
17 over to the regular, normal, full blown-out rulemaking
18 regulatory process.

19 So it is not to say that NRC staff is not
20 being responsive. It is not saying that we are not
21 taking action. It really depends on what the action
22 is.

23 For example, the information notice that
24 Dr. Tapp referenced yesterday. The staff did take an
25 action. They were evaluating it and, based on their

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1 evaluation, it spurred into something else.

2 So I guess my bottom line is to say we are
3 doing something. We are taking action. It depends
4 on what that particular action is.

5 CHAIRMAN PALESTRO: Thank you, Ms.
6 Holiday.

7 Mr. Einberg.

8 MR. EINBERG: Yes, just to add on to what
9 Sophie had to say, I think the frustration from the
10 ACMUI members may be that they don't understand why
11 it is taking so long. So when we go through the action
12 items that we explain that this is where we are in the
13 process on this particular item so that they have an
14 understanding that it is in rulemaking, rulemaking
15 takes X number of years and this is where we are in
16 the process, so that they don't have that frustration
17 and that they see that these items are being acted upon.

18 Regarding the frequency of meetings, I
19 would also add that another option would be to have
20 three-day meetings, rather than two-day meetings if
21 there are additional topics that need to be discussed.

22 CHAIRMAN PALESTRO: Thank you. Mr.
23 Ouhib.

24 MEMBER OUHIB: Yes, I guess just to answer
25 the concern about you know perhaps things are not being

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1 done as expected, which I am not sure I agree with that,
2 is to sort of have some projected target dates, more
3 or less, but they are not set in stone, knowing that
4 sometimes, for whatever reason, there are things that
5 will take longer. But at least having some target date,
6 people will sort of have an idea of what to expect.

7 MR. EINBERG: Yes, excellent idea.

8 CHAIRMAN PALESTRO: Any other comments or
9 questions from the committee?

10 Attendees in the room?

11 Bridge line?

12 All right, I am just going to add one final
13 comment because we are really out of time on this
14 session.

15 And I think it would be helpful for the
16 fall meeting to include a session and explain how the
17 items that the ACMUI itself acts on or recommendations
18 we make, how they go through the pathway to final
19 resolution, like rulemaking and so forth, and give us
20 a sense of the time it takes for each of these things.

21 Because I have been on the committee for eight years
22 and I know that it takes a long time to get many items
23 accomplished but if you were to ask me specifically
24 what path, I don't have that answer, that knowledge
25 and I think it would be helpful to us. It would give

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1 us a much better understanding.

2 Any other comments or questions?

3 All right, that concludes this session.

4 Thank you.

5 And now we are ready for the next, which
6 is a special presentation to Ms. Laura Weil, our
7 patients' rights advocate. And Mr. Moore will make
8 this presentation.

9 MR. MOORE: Good morning, ACMUI. Good
10 morning, Chairman. Good morning, Dr. Weil.

11 I am Scott Moore. I am the Deputy Director
12 for the Office of Nuclear Material Safety and Safeguards
13 and today I am here to recognize Dr. Weil with the ACMUI,
14 her contributions to the committee, and to the NRC.

15 This is Dr. Weil's last in-person meeting
16 as the ACMUI Patients' Rights Advocate. Dr. Weil was
17 appointed as the ACMUI Patients Rights' Advocate in
18 2011 and will be completing her second and final term
19 on August 28th, 2019. She serves in a unique and vital
20 role on the ACMUI because the patients' rights advocate
21 serves as a liaison between patients and the healthcare
22 providers on the committee.

23 Patient care is of the utmost concern to
24 the NRC and we are interested in that because byproduct
25 material, obviously, is used to treat and diagnose

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1 diseases and cancers.

2 She has briefed the Commission during
3 public Commission meetings on a number of occasions,
4 since she has been with the committee, including in
5 2012 -- actually, every year that she has been on the
6 committee from 2012 until today. In 2012 she talked
7 about medical events, 2013 she talked about patient
8 release, 2014 she talked about radiation safety
9 instruction, 2015 was patients' rights, 2016 was more
10 about patients' rights, 2017 was training and
11 experience, 2018 was a number of different topics, it
12 was three separate topics on T&E recommendations for
13 revisions to patient release and medical event
14 reporting. And then she is again reporting to the
15 Commission today on nursing mothers' guidelines, T&E,
16 and medical event reporting.

17 So she has the honor of having briefed the
18 Commission more than anybody else on the committee,
19 at this point, which may be a dubious honor. So it
20 depends on how you look at it, I guess. If you are
21 a problem licensee, you don't want to be in that place.

22 Anyway, we appreciate your doing that, Dr.
23 Weil, and the Commission appreciates it, too.

24 You have worked with NRC staff to develop
25 a Federal Register notice to request information from

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1 the public on patient information and guidance existing
2 on websites and available brochures. And most
3 recently, you provided the staff in our office with
4 comments on the patient release brochure.

5 Since being on the committee, she has
6 attended a number of thyroid cancer survivors' meetings
7 in her role as the patients' rights advocate. And in
8 addition to the things that I just mentioned, we have
9 also benefitted from her experience on a number of high
10 priority issues, including hormesis linear
11 non-threshold, abnormal occurrence reporting, proposed
12 amendments to the ACMUI bylaws, proposed revision to
13 our NRC policy statement on abnormal occurrence
14 reporting, the issue of the 700 hours training and
15 experience, the impact of medical event reporting on
16 medical licensee patient safety, patient intervention,
17 and the physical presence requirements for the Leksell
18 Gamma Knife.

19 She also served as the chair of the 2019
20 ACMUI Bylaws Subcommittee.

21 So at this time, we would like to present
22 you with a few tokens of our appreciation. Sophie,
23 I would like to ask you to come up, and Dr. Weil.

24 MEMBER WEIL: I appreciate the promotion
25 but I am not a doctor.

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1 MR. MOORE: Oh, I'm sorry, Ms. Weil, yes,
2 actually.

3 So Sophie, if you could hand this to her.
4 Yes, and Kellee, too. Yes.

5 We have a flag that was flown over the
6 Capitol and a certificate from Senator Van Hollen; a
7 certificate of appreciation from Chairman Svinicki;
8 and finally, a gold lapel pin from the NRC.

9 And so I would just like to tell you from
10 myself, from the staff, and from the NRC as a whole,
11 thank you so much for your service. The Patients'
12 Rights Advocate is a very important role for us, the
13 staff. The committee, as you all know, is filled with
14 medical experts, with government officials, with
15 states' representatives but the patients' rights
16 advocate plays an extremely important role.

17 To us, you know you are representing
18 patients that are out there and we listen very heavily
19 to the comments that you provide. You have been on
20 the committee for a long time and we really, really
21 appreciate your input. So thank you from the staff
22 and from the agency.

23 Would you like to make any comments?

24 MEMBER WEIL: Yes, but I would like to sit
25 down.

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1 MR. MOORE: Okay, great. Thanks.

2 MEMBER WEIL: Well thank you very much for
3 reminding me of all the things I've been engaged in
4 because I had forgotten most of that.

5 When I first began my first term on the
6 ACMUI, I was prepared to face a fair amount of suspicion,
7 if not outright hostility in my role as a professional
8 patients' advocate.

9 Someone who calls herself a patients'
10 advocate needs always to be ready for the dangers of
11 usurping that title from others who justifiably see
12 themselves as advocates as well. Almost everyone who
13 works in the healthcare arena has opportunities to
14 advocate for what patients need and often, the front
15 line workers are the unsung heroes in this endeavor.

16 But I was surprised that there was very
17 little, if any, of that reaction here at NRC. And as
18 you will hear me state to the Commissioners, I believe
19 that just about every one of the ACMUI members I have
20 had the privilege to work with over the last nearly
21 eight years has considered patient advocacy an
22 essential core of his or her professional ethic.

23 In my academic career, I used to tell my
24 students that there is patient advocacy with a small
25 p and patient advocacy with a capital P. And that

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1 uppercase P represents a more zoomed-out perspective,
2 advocating for groups and populations, rather than the
3 needs of a single small p patient.

4 The uppercase P is certainly the focus of
5 advocacy here at the ACMUI and it needs to be
6 differentiated from what most healthcare workers can
7 accomplish in the course of their often overwhelming
8 primary responsibilities. The uppercase P is what has
9 driven my belief that it is perfectly appropriate for
10 a regulatory agency like NRC to require and not just
11 recommend guidance timely education for patients who
12 are administered radiopharmaceuticals such that they
13 are able to understand, and plan, and effectively
14 protect those around them from unnecessary exposure
15 to radiation. That's a public health issue and it isn't
16 stepping on the toes of the practice of medicine.

17 The uppercase P drives the need to make
18 sure that healthcare providers are competent to use
19 radiopharmaceuticals and have received appropriate
20 training and experience. Indeed, the uppercase P
21 drives much of what the ACMUI tries to accomplish in
22 terms of promoting safety, accessibility, and fairness.

23 That uppercase P also prompted me to
24 repeatedly remind the committee that all of the
25 distinguished professionals in this room work at

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1 Centers of Excellence and represent the best of the
2 best in health care. And everyone needs to remember
3 that not all patients experience health care the way
4 it is provided in your facilities. Not all medical
5 personnel have the support that is likely provided in
6 the facilities where you work.

7 Regulation needs to be appropriate for the
8 best facilities but more essentially, it needs to ensure
9 protections for patients and workers in those
10 less-than-best environments, where most health care
11 is delivered in the United States.

12 It has really been a privilege to serve
13 with you and I wish you the very best going forward.

14 MR. MOORE: Congratulations, Ms. Weil.
15 I would like to thank the committee and the chairman
16 for the opportunity to recognize Ms. Weil as well as
17 her briefings to the Commission. And if anybody beats
18 her record of eight presentations to the Commission
19 -- we are keeping track. So, congratulations.

20 MEMBER WEIL: Thanks.

21 MR. MOORE: Mr. Chairman.

22 CHAIRMAN PALESTRO: Laura, you and I have
23 been on the committee for just about the same length
24 of time and I have always come to think of you as the
25 conscience of the committee, reminding us that, as we

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1 are going through our various discussions about
2 education and experience, and the various rules and
3 regulations, and so forth, reminding us that
4 ultimately, at the end of the day, it is centered on
5 the best in care and safety for the patient. The
6 patient is of the utmost importance.

7 Now on a personal note, Northwell Health
8 owes you a vote of thanks. A few years ago you had
9 presented the results of a survey that you had done
10 on patients with thyroid cancer. And one of the things
11 that you -- you discussed many things but one of the
12 things that you discussed that stuck in my mind because
13 I am responsible for several institutions, was the
14 variation in instructions that patients got from one
15 institution or one physician to another and how
16 disconcerting that was, not necessarily that the
17 instructions, the variations were wrong or incorrect
18 but there were variations and the patient didn't know
19 what to do.

20 And so I decided that it was time probably
21 to go back and relook at what I had assumed to be
22 consistent instructions from site to site and found
23 that they weren't so consistent and that they did vary.

24 And as the patients moved from one institution to
25 another, they would get one set of instructions or

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1 another and that clearly caused them angst.

2 So as a result of your comments and my
3 review of that, it took us a while, but I think that
4 you would be pleased to know, and I know that our
5 patients are, that we finally have it down, for at least
6 our thyroid cancer patients, to a uniform set of
7 instructions and guidelines. And for that, we are
8 deeply indebted. Thank you.

9 Anyone else who would like to say anything?

10 Dr. Ennis.

11 MEMBER ENNIS: I just wanted to echo what
12 other people have said, that in the almost four years
13 I have been on the committee, I have always found your
14 comments to be extremely thoughtful, sharpening the
15 debate, the discussion, extremely well expressed, and
16 always a significant contribution to any conversation.

17 So personally, I have enjoyed getting to
18 know you and forming a friendship as well but your
19 professional contributions go beyond the specific
20 presentations that you have made but the role that you
21 have had in regular discussions and all your
22 subcommittees has just been really extremely valuable.

23 CHAIRMAN PALESTRO: Any other comments?

24 Dr. Metter.

25 VICE CHAIRMAN METTER: I haven't been on

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1 the committee as long as everybody else. This is, I
2 believe, my third year. And I have always looked
3 forward to your wise comments, your excellent delivery.
4 And you were not afraid.

5 And as far as the patients' rights
6 advocate, if a patient were here, I mean they would
7 be very proud of what you stand for for them.

8 And you know there would be discussion and
9 then all of a sudden, Laura's hand would go up and there
10 would be like uh-oh. And the thing is that you would
11 bring a perspective that we are so tunneled in that
12 it would be oh, yes, I forgot about that. And something
13 like what Dr. Palestro said, you know something we take
14 for granted that you bring up and really you are a true
15 patient advocate.

16 And thank you for all the work that you
17 do and really you've opened up the ACMUI to even getting
18 better in what they do. Thank you.

19 CHAIRMAN PALESTRO: Mr. Ouhib.

20 MEMBER OUHIB: Yes, I just want to thank
21 you, Laura, for everything you've brought to the table.

22 It's always good to have a compassionate
23 person that reminds everybody that numbers are good,
24 rules are good, but I think more than everything else,
25 don't forget to be compassionate in everything you do

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1 because that is what it will come down to. Thank you.

2 CHAIRMAN PALESTRO: Anyone else?

3 Mr. Einberg.

4 MR. EINBERG: Yes, hi, Laura.

5 So I hired, Laura. I was one of the people
6 who interviewed Laura. And when we went out and were
7 looking for a patients' rights advocate in the position,
8 this is a very difficult position to fill, and we really
9 lucked out with Laura. She has made tremendous
10 contributions to the ACMUI. She has been conscious
11 of the staff here and she has done wonderful.

12 And so we are in the process of looking
13 for a new ACMUI patients' rights advocate and that is
14 going to be a very tough position to fill and very big
15 shoes to fill.

16 So thanks once again. And any advice you
17 have for us regarding what we should look for in a future
18 patients' rights advocate would be appreciated and we
19 can talk offline about that.

20 Thank you.

21 CHAIRMAN PALESTRO: Anyone else?

22 Dr. Howe.

23 DR. HOWE: I've probably seen more ACMUI
24 meetings than anyone else in this room and I have been
25 through -- probably including Scott -- and I've been

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1 through a number of different patients' rights
2 advocates that we have had on the ACMUI. And I have
3 to tell you Laura has set the bar extremely high. She
4 has been one of the best patient advocates we have had.

5 And I hope in the future we are able to
6 make a decision that brings a new patient advocate in
7 that will meet her high standards because it has been
8 very important to the ACMUI to have that different
9 perspective and she has contributed a tremendous amount
10 to the NRC and the ACMUI.

11 Thank you, Laura.

12 CHAIRMAN PALESTRO: Dr. Dilsizian.

13 MEMBER DILSIZIAN: Well, Laura, when I
14 joined the ACMUI, I had no expectation of what the
15 patient advocate was going to be promoting, except my
16 experience with the IRBs. I had a lot of patient
17 advocates in the IRB meetings. You know usually their
18 comments are directed to the patient consent form,
19 understanding of the wordings, et cetera.

20 But I have learned so much from you. I
21 have served in so many committees with you. Not only
22 do you provide insight, you also are -- you edit a lot
23 of our reports very accurately and correctly. And I
24 have to say that you have also taught me that our
25 perspective here is really, as you said, from university

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1 hospitals, where we tend to forget. And several times
2 you pointed out to me, I said this is how we do it at
3 Maryland and you said but that's not normal. And then
4 that was kind of unusual for me to hear that and I think
5 I learned a lot from you. And yes, I have a different
6 perspective.

7 And I also respect that you are willing
8 to change your mind. A lot of times, you start with
9 a certain opinion. After discussions, you kind of
10 change. And that is big.

11 Thank you very much.

12 CHAIRMAN PALESTRO: Anyone else?

13 MS. HOLIDAY: Does anybody before I go?

14 Okay. So unlike Donna-Beth, I have not
15 been around for as many ACMUI meetings but I have been
16 around for all of Ms. Weil's ACMUI meetings. And after
17 hearing what everybody has said, you know it is
18 absolutely true.

19 And one of the remarkable things about Ms.
20 Weil is that she is so humble. You were humble every
21 time you were placed on a subcommittee. And she is
22 the first person to say, you know I am not the subject
23 matter expert and I don't have any technical expertise
24 but then you come in and you add so much value to the
25 discussions, to the report. You have wordsmithed the

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1 heck out of everything, out of our patient release
2 brochure. The staff has reached out to Ms. Weil on
3 numerous occasions as it relates to patient release.

4 And we are very, very fortunate to have
5 had you here on the committee. We have been around
6 for the birth of children, for the birth of
7 grandchildren. We are the fellow
8 vertically-challenged people and I am happy to be able
9 to call you a friend.

10 So congratulations and thank you.

11 CHAIRMAN PALESTRO: Anyone else?

12 All right, Laura, I think what we've heard
13 sums up everything about you and, again, on behalf of
14 myself and the committee, everyone here, our sincere
15 thanks for your eight years of service and we hope we
16 don't lose touch.

17 Thank you very much.

18 All right, that concludes this session.
19 We are on a break now until ten o'clock. The Commission
20 meeting is in White Flint One. All right, very good.

21 We will see you there. Thank you.

22 (Whereupon, the above-entitled matter went
23 off the record at 9:25 a.m. and resumed at 1:15 p.m.)

24 CHAIRMAN PALESTRO: All right, welcome
25 back. We will call this afternoon's final session to

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1 order.

2 Before we proceed into the formal part of
3 the program, I just want to thank Doctors Metter, Ennis,
4 and Ms. Weil for their contributions and presentations
5 at this morning's session with the Commission. It
6 certainly -- obviously, I am prejudiced because I was
7 part of it, but I think it was the best of all the
8 sessions that I have been involved with the
9 commissioners. I thought it was an excellent dialogue
10 and I received compliments from many people. And I
11 really appreciate that and it really goes to all of
12 you folks.

13 And in fact some woman, who I have no idea
14 who she was, stopped me on the street and said good
15 meeting, Palestro. So, whoever it was, I think we did
16 a good job.

17 (Laughter.)

18 CHAIRMAN PALESTRO: That may be a custom
19 here in Rockville and Bethesda.

20 So thank you all very much. I appreciate
21 that job well done.

22 All right. So we are going to move on to
23 the next topic, the ACMUI Bylaws Subcommittee Report
24 and Ms. Weil will present this.

25 MR. WILLIAMS: Dr. Palestro, if I could,

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1 I want to correct the record.

2 Thank you. Before we get into the
3 presentation, I wanted to -- before the break and Mike
4 Fuller and I had this conversation during the Commission
5 meeting, I wanted to just correct one thing on the
6 record.

7 We were talking about the advantages or
8 disadvantages of ACMUI reporting either to the
9 Commission or staying at the same place with reporting
10 to the Division Director. And one of the comments that
11 was made is that the -- and I am paraphrasing but that
12 the staff had nothing to offer.

13 And what I wanted to correct was the staff
14 has a vast amount of knowledge and expertise in terms
15 of health physics and things of that nature. What is
16 being supplemented is the vast expertise that the ACMUI
17 Committee brings in a variety of areas that we -- you
18 know so we have identified the gap. And together, I
19 think we work very well and complement each other, and
20 we are able to provide and address a number of
21 activities.

22 So, thank you.

23 CHAIRMAN PALESTRO: Thank you, Mr.
24 Williams.

25 All right, now we are going to proceed to

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1 the Bylaws Subcommittee report with Ms. Weil.

2 MEMBER WEIL: Thank you. Can I have the
3 next slide? Do I have control of the slides? Thank
4 you.

5 So I would like to thank my fellow
6 subcommittee members, Robert Schleipman, Michael
7 Sheets, Megan Shober, and our staff resource was Sophie
8 Holiday.

9 The subcommittee charge was to review the
10 ACMUI Bylaws and recommend updates, with particular
11 focus on the question of whether the ACMUI chair may
12 serve as a member or a chair of any subcommittee.

13 So we considered two issues. Should the
14 ACMUI chair be allowed to participate in the
15 subcommittees and, if so, in what capacity? And what
16 language, if any, should be added to the bylaws to
17 clarify this question?

18 And we also considered whether there were
19 any other clarifications or additions to the ACMUI
20 bylaws that should be considered.

21 Regarding the ACMUI chair participation
22 on subcommittees, it has been the practice of the NRC
23 to prohibit the participation of the ACMUI chair in
24 subcommittee deliberations and recommendations. This
25 was recently brought to the attention of the incoming

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1 ACMUI chairman, Dr. Palestro, who was asked to
2 relinquish his position as chair of an ongoing
3 subcommittee in anticipation of his role as ACMUI
4 chairman.

5 Dr. Palestro felt that this issue should
6 be investigated by a subcommittee and an explicit
7 recommendation be made to the ACMUI with potential
8 clarification in the ACMUI bylaws. The current ACMUI
9 chair and vice-chair would not vote on the
10 recommendation put forth by this subcommittee.

11 ACMUI bylaws do not address this point,
12 nor does the ACMUI charter. The documents of our sister
13 NRC Federal Advisory Committee, the Advisory Committee
14 on Reactor Safeguards, is also generally silent on the
15 issue, although the ACRS chair is the designated chair
16 of a standing subcommittee. We don't have standing
17 subcommittees.

18 There is no discussion of this issue on
19 the FACA website, nor did consult with FACA staff
20 suggest any required position on the issue.

21 Several other FACA committee bylaws and
22 charters were reviewed by the subcommittee and none
23 had explicit language regarding the potential for chair
24 membership and participation in subcommittee work.

25 The understood rationale for the existing

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1 informal prohibition is that the role of the chair is
2 onerous and time-consuming and it would be an imposition
3 to expect the chair to undertake additional -- is this
4 slide 4? Do we have slide 4? It doesn't matter. We
5 can go forward -- to undertake any additional
6 responsibilities.

7 And the second rationale is that the chair
8 might, exert undue influence on subcommittee
9 deliberations.

10 Can you go forward to slide 4? Okay.

11 Section 1.3.6 of the ACMUI Bylaws
12 explicitly states the chair may take part in the
13 discussion of any subject before the ACMUI and may vote.

14 The chair should not use the power of the chair to
15 bias the discussion. And any dispute over the chair's
16 level of advocacy shall be resolved by a vote on the
17 chair's continued participation in the discussion of
18 the subject.

19 Each member of the ACMUI has a specific
20 area of expertise and in some cases, there is no
21 duplication of expertise among all members. The
22 subcommittee felt that any subcommittee should be able
23 to avail itself of the relevant expertise of any member
24 of the ACMUI. The potential for benefit of any given
25 subcommittee outweighs the potential for undue

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1 influence by the position of the chair.

2 So here is an example. Recent
3 subcommittee relating to gamma stereotactic
4 radiosurgery licensing guidance, only one member of
5 the ACMUI had specific and significant GSR experience.

6 Had that member been the ACMUI chair and prohibited
7 from subcommittee participation, the subcommittee
8 would have been deprived of essential information and
9 input in its deliberations.

10 Concern was expressed that the ACMUI
11 chair's participation on a subcommittee should not
12 overburden or compromise the ability of the chair to
13 perform the duties of ACMUI chair. So it is proposed
14 that the ACMUI chair not be asked to serve as a
15 subcommittee chair.

16 The subcommittee also discussed whether
17 explicit bylaws language is required to address the
18 question or whether a formal position expressed and
19 captured in the ACMUI meeting would be adequate. The
20 membership of the ACMUI turns over completely every
21 eight years or sooner and NRC staff rotate in and out
22 of the medical team with unpredictable frequency. It
23 is challenging to research areas of tradition and
24 practice such as this. The minutes and transcripts
25 of ACMUI meetings, while available, aren't indexed by

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1 subject.

2 It was felt that there are potential limits
3 to ACMUI institutional memory such that inclusion of
4 specific language in the bylaws would be beneficial
5 and the most efficient way to address this issue.

6 New language is suggested to be inserted
7 in the existing bylaws regarding ACMUI chair
8 discussion, participation, and voting rights. So this
9 would go into 1.3.6 and we suggest amending the
10 statement with in matters where the ACMUI chair's unique
11 experience and knowledge would be especially
12 informative, the chair may serve on relevant
13 subcommittees. In these instances, the ACMUI chair
14 will not chair the subcommittee.

15 With respect to additional bylaws
16 additions, the subcommittee felt that the existing
17 language in the bylaws regarding conflict of interest
18 was vague.

19 The bylaws currently state, under Section
20 4, Conduct of Members, if a member believes that he
21 or she may have a conflict of interest with regard to
22 an agenda item to be addressed by the ACMUI, this member
23 should divulge it to the chair and the DFO as soon as
24 possible and before the ACMUI discusses it as an agenda
25 item. ACMUI members must recuse themselves from

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1 discussion of any agenda item in which they have a
2 conflict of interest.

3 The subcommittee suggests that the bylaws
4 be amended with additional language to identify more
5 clearly what constitutes a conflict of interest.

6 The following language -- can you go to
7 the next slide -- is used in the ACRS bylaws, Section
8 10.2-2, defining what constitutes a financial conflict
9 of interest and we think it should be inserted or
10 considered for amending the ACMUI bylaws.

11 And this is what is in the ACRS bylaws and
12 it is pretty simple. It just identifies that a
13 financial conflict would directly or predictably affect
14 the personal financial interest of a spouse, minor
15 child, the organization in which they serve as an
16 officer, director, trustee, general partner, or
17 employee, an organization in which they are negotiating
18 or have an arrangement for prospective employment.

19 However, the subcommittee welcomes staff
20 input on other language that would still provide
21 adequate clarification if this is not thought to be
22 useful.

23 So, in summary -- next slide -- we recommend
24 that the ACMUI chair should be permitted to serve as
25 a subcommittee member, not chair, when his or her

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1 specific expertise is necessary and a specific
2 statement to that effect should be included in the ACMUI
3 bylaws.

4 And the subcommittee recommends that more
5 explicit language be included in the bylaws defining
6 conflict of interest with respect to participation of
7 individual ACMUI members in discussion of matters that
8 come before the committee.

9 Thank you.

10 CHAIRMAN PALESTRO: Any comments from
11 other members of the subcommittee?

12 MEMBER SCHLEIPMAN: I have one comment.
13 The second slide erroneously refers to me as M.D. I
14 guess I got promoted like you earlier today. So just
15 for the record that that could be removed.

16 CHAIRMAN PALESTRO: Any other comments or
17 questions from the subcommittee? From the committee?

18 Mr. Ouhib.

19 MEMBER OUHIB: Yes, can we go back to slide
20 number 8, please? I'm not sure if I am in favor of
21 that statement members cannot participate in the review
22 of any particular matter.

23 I think as long as the conflict of interest
24 is disclosed, okay, to the chair, basically, or to the
25 subcommittee, or whatever, I don't see why that member

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1 should not participate without voting, per se. Because
2 that person might very well have valuable information
3 to the committee but then they will up-front disclose
4 as the conflict comes because six months from now there
5 was no conflict but all of a sudden now, there is a
6 conflict.

7 They can simply disclose it at the very
8 beginning but then they should be able to participate
9 but perhaps they should not be voting.

10 CHAIRMAN PALESTRO: This issue actually
11 came up, I believe, at the last meeting and there was
12 in fact a conflict of interest or a potential conflict
13 of interest and it was decided that individual could
14 not participate on the subcommittee.

15 And in fact a decision, and correct me if
16 I am wrong, Ms. Holiday, but that decision really went
17 beyond the ACMUI's choice. That went I guess through
18 legal. Is that right?

19 MS. HOLIDAY: That is correct. And just
20 for clarification, in the existing ACMUI bylaws Section
21 4.1, the language specifically states if a member
22 believes that he or she may have a conflict of interest
23 with regard to an agenda item to be addressed by the
24 ACMUI, this member should divulge it to the chair and
25 the DFO as soon as possible and before the ACMUI

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1 discusses it as an agenda item. ACMUI members must
2 recuse themselves from discussion of any agenda item
3 in which they have a conflict of interest.

4 This is also covered in your annual ethics
5 training. As it so happens, we have some
6 representatives from the Office of General Counsel
7 here.

8 MS. HOUSEMAN: Hi, Esther Houseman --

9 MS. HOLIDAY: Esther, you have to push the
10 button. There is a gray button.

11 MS. HOUSEMAN: Esther Houseman, Office of
12 the General Counsel.

13 I just want to quickly point out that it
14 looks to me like this provision from the ACRS bylaws
15 is a restatement of the Office of Government Ethics
16 rule on financial conflict of interest. So these are
17 actually Office of Government Ethics requirements and
18 nothing in the ACMUI's or the ACRS's charter, or bylaws,
19 or NRC regulations can change that.

20 And so if you are to revise the conflict
21 of interest provisions in the ACMUI bylaws, in addition
22 to the staff, the NMSS staff, the Office of the General
23 Counsel can review those and provide input to ensure
24 that they align with the Office of Government Ethics
25 rules.

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1 MS. HOLIDAY: Thank you.

2 And just to follow-up to what Ms. Houseman
3 just said, Section 5.4 of the bylaws says the ACMUI
4 shall consult with the Office of General Counsel
5 regarding conflicts that arise from the interpretation
6 of the bylaws. After consultation, the ACMUI shall
7 resolve interpretation issues by a majority vote of
8 the current membership of the ACMUI.

9 So basically, the process -- I don't see
10 many members here from back when we passed the bylaws
11 in 2014, except for maybe the latter part of this table.

12 The ACMUI had made recommendations to change the bylaws
13 in 2014. So after we revised those bylaws in a public
14 meeting, so that everybody could see the language that
15 was proposed and agreed to, it had to go through our
16 Office of General Counsel for them to give us what they
17 call a no legal objection, meaning that there is nothing
18 legally objectionable to it. And that from there, it
19 could be finalized.

20 So as Ms. Houseman stated, this language
21 is directly from OGE, the Office of Government Ethics.

22 It is a more detailed explanation than what is
23 currently in our bylaws. So all Ms. Weil's
24 subcommittee was doing was wanting to update the
25 language that I had initially read to correspond to

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1 the language that is verbatim from OGE and,
2 coincidentally, captured in the ACRS bylaws.

3 CHAIRMAN PALESTRO: Thank you, Ms.
4 Holiday.

5 Dr. Dilsizian.

6 MEMBER DILSIZIAN: Yes, I completely
7 agree. I think that even if -- if you have a conflict
8 and you are in the discussion, period, you can convince
9 other people's minds. So that is the reason I think
10 it should be completely -- and you know any
11 organization, any meeting, any Board of Directors, if
12 you remember, you always recuse yourself. You never
13 really try to convince the others.

14 Even though your expertise may be unique,
15 I think that this is the proper way, in my opinion.

16 Now regarding your presentation, Laura,
17 I think could you go back to maybe six, slide 6?

18 Okay, so I agree with you that the concept
19 that if the chair has unique experience, obviously,
20 he should serve as a member. You say in these
21 circumstances, the ACMUI chair will not chair the
22 subcommittee.

23 In my opinion, it is not only in these
24 instances. In any other instances, the chair should
25 not chair a subcommittee. You know what I am saying?

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1 It just seems like others --

2 MS. HOLIDAY: So is there a motion on the
3 table to amend the recommendation?

4 CHAIRMAN PALESTRO: I am not done.

5 MS. HOLIDAY: Sure.

6 CHAIRMAN PALESTRO: Ms. Weil, you are
7 reporting the case that the ACMUI chair, under certain
8 circumstances, can serve on a subcommittee. The
9 question is, who makes the determination, the
10 subcommittee chair or the ACMUI chair?

11 MEMBER WEIL: So the ACMUI chair would be
12 establishing the subcommittee, correct? You establish
13 our subcommittees.

14 CHAIRMAN PALESTRO: That's correct.

15 MEMBER WEIL: And so I would think that
16 it would be the chair of the subcommittee. You choose
17 a subcommittee. The chairman of the ACMUI --

18 CHAIRMAN PALESTRO: That's correct, yes.

19 MEMBER WEIL: -- chooses the subcommittee,
20 designates a chair of that subcommittee, and that chair
21 then would be the person to request the participation
22 of the appropriate specialist, who happens to be the
23 ACMUI chair.

24 CHAIRMAN PALESTRO: Thank you.

25 Mr. Sheetz.

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1 MEMBER SHEETZ: I just want to comment on
2 that. I would think that the chair would be able to
3 appoint him or herself to the subcommittee and, if the
4 chair did not appoint him or herself to subcommittee,
5 the subcommittee chair could ask the chair to serve
6 on that committee, should they feel that that expertise
7 was necessary.

8 That covers all ends.

9 CHAIRMAN PALESTRO: Dr. Ennis.

10 MEMBER ENNIS: So the point of these kinds
11 of rules are to avoid abuse of power. It feels a little
12 like okay, that's not going on. Now we're all getting
13 along and all of that. But the point of this is well
14 what happens if there is an issue, which has happened
15 in the past, from what we understand. Most of us
16 weren't here then.

17 So I feel a little uncomfortable about the
18 notion that the chair appoints his friend, who then
19 will turn around and appoint his friend back on the
20 committee. That feels too cozy and allows for a little
21 bit of abuse of power over what kind of relationship
22 those two might have in all kinds of ways.

23 So I would prefer that this exception in
24 allowing the chair to be on a subcommittee be something
25 that either the entire ACMUI has to vote on or the

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1 subcommittee in its entirety has to vote on.

2 MS. HOLIDAY: Dr. Ennis, thank you for
3 raising that point. So I will also read for you Section
4 1.3.6 of the bylaws. And it states the chair may take
5 part in the discussion of any subject before the ACMUI
6 and may vote. The chair should not use the power of
7 the chair to bias the discussion. Any dispute over
8 the chair's level of advocacy shall be resolved by a
9 vote on the chair's continued participation in the
10 discussion of the subject.

11 So one could say that you could either
12 reference Section 1.3.6, if that is the recommendation
13 of the committee, you can model it after the language
14 in Section 1.3.6. But I do want to make you aware of
15 the language that is currently in the bylaws.

16 MEMBER WEIL: What we are suggesting is
17 that this statement follow and be included in 1.3.6
18 but be included in that paragraph.

19 CHAIRMAN PALESTRO: Any other comments or
20 discussion?

21 Comments/questions from attendees in the
22 room? Bridge line?

23 Dr. Howe.

24 DR. HOWE: I just had a question. When
25 you are proposing to change the conflict of interest,

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1 it seems to be only addressing financial reasons.

2 In some cases in the past, we have had --
3 and I don't think this would be necessarily financial,
4 but we have had cases where maybe a member of the ACMUI
5 has a licensing action in front of the NRC and that
6 might be a conflict of interest for that person to be
7 actively representing a certain position on that type
8 of licensing action.

9 So I think the conflict of interest is a
10 little broader than just financial. I think you should
11 consider.

12 CHAIRMAN PALESTRO: Ms. Weil, any comments
13 on that?

14 MEMBER WEIL: Yes, I looked at other
15 conflict of interest statements in other advisory
16 committee bylaws and they can run to several pages.
17 And I guess I would rely on our counsel to suggest
18 whether or not our bylaws need additional language,
19 or whether the statement -- well, not counsel -- on
20 us to decide whether we need additional language or
21 whether or not we just can rely on that statement where
22 we refer back.

23 I felt there needed to be further
24 clarification because conflicts do come up in this
25 committee. They do come up and we had one recently.

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1 And I think we could all use a bit of guidance.

2 I guess I would love to open this to
3 subcommittee members about whether you think we need
4 the broad description of conflict.

5 MEMBER SCHLEIPMAN: So this is Robert.

6 I agree with Dr. Howe that there can be
7 other conflicts. And the existing language in 4.1
8 permits all of the -- you know more than financial
9 conflicts to be addressed or reviewed.

10 I think what you are asking, perhaps, or
11 suggesting is that all of the committee members have
12 a clear understanding of what types of situations may
13 constitute a conflict. Most people know but perhaps
14 we are not regularly familiar with the Code of Ethics,
15 although we have reviewed it and so forth.

16 And so if there is just a reference to what
17 are the descriptions for a conflict of interest, that
18 may be fine, rather than substituting the broader
19 language, which permits consideration of all types of
20 conflicts.

21 CHAIRMAN PALESTRO: Mr. Green.

22 MEMBER GREEN: In light of the comment to
23 be not quite so specific, to focus purely on financial
24 interest, if we go to slide 8 in the proposed language,
25 as proposed by the subcommittee, if we struck the word

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1 financial out of the fourth row, to predictably affect
2 their personal interest or the financial -- or again,
3 I guess we would strike financial twice out of that
4 first paragraph. If we struck that word out twice,
5 then it is not solely focused on financial matters but
6 also include licensing activities of all of these items
7 below.

8 MEMBER WEIL: I believe we just heard that
9 we can't alter the language, that we need to use the
10 language that already exists.

11 MS. HOUSEMAN: OGC would review whatever
12 proposal you put forth and could assist in drafting
13 language, again, that aligns with the government ethics
14 rules. And it all depends on just to what extent do
15 you want to summarize and incorporate the government
16 ethics rules into your bylaws to serve as just an
17 additional place where you can look to think about is
18 there a conflict of interest here.

19 I don't think that striking the term
20 financial would work, again, because I think that this
21 restatement captures specifically the financial
22 conflict of interest government ethics rule.

23 MEMBER WEIL: Is there a reference
24 document that we can refer to in the bylaws that --
25 rather than restating it, can we just reference it as,

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1 Dr. Schleipman asked?

2 MS. HOUSEMAN: We could find the
3 regulatory references so to the particular government
4 ethics rules, if that is what you are asking.

5 MEMBER WEIL: That might be the most
6 efficient way to approach this.

7 MS. HOUSEMAN: It might be, yes.

8 MEMBER WEIL: Efficient is good.

9 CHAIRMAN PALESTRO: Mr. Ouhib.

10 MEMBER OUHIB: Yes, just I would make a
11 suggestion. Perhaps for every subcommittee at the
12 beginning of each session to sort of remind people about
13 the conflict of interest to state that. And that is
14 very common in several medical organizations when there
15 is a task group or whatnot to actually at the very
16 beginning state that if you have any conflict of
17 interest to state it now and remove yourself. Because
18 you just never know. It is sort of like reminding
19 people about that policy.

20 CHAIRMAN PALESTRO: Mr. Ouhib, just so
21 that it is clear in my mind what you said, that you
22 would like to have a conflict of interest reviewed at
23 the beginning of every meeting and every telephone
24 conference?

25 MEMBER OUHIB: Not necessarily review it

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1 but state it sort of as a reminder to people that if
2 you have a conflict of interest, that you need to remove
3 yourself from any discussion that is going to take
4 place.

5 CHAIRMAN PALESTRO: I think that that is
6 an excellent point.

7 Mr. Einberg.

8 MR. EINBERG: Maybe we could add that to
9 the opening remarks.

10 CHAIRMAN PALESTRO: Thank you.

11 Any other comments or questions?

12 All right. In terms of the subcommittee's
13 report, it has actually got two separate components
14 and I would ask Ms. Weil and the subcommittee what do
15 you think about deferring a vote on the conflict of
16 interest until such time as legal provides us with a
17 more comprehensive or more appropriate, if you will,
18 definition?

19 MEMBER WEIL: I would suggest that the
20 report should be amended to remove the in these
21 instances statement. So the chair may serve on
22 relevant subcommittees. The ACMUI chair will not chair
23 the subcommittee. So that recommendation is amended
24 to remove those three words: in these instances.

25 CHAIRMAN PALESTRO: And you add that the

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1 ACMUI chair will serve on a subcommittee at the
2 subcommittee's discretion.

3 MEMBER WEIL: Yes.

4 Okay and regarding the conflict of
5 interest, I would suggest that the report be amended
6 to state the same things, the subcommittee felt that
7 the existing language in the bylaws regarding conflict
8 of interest was vague. And then there is the citation
9 of Section 4, Conduct of Members, which describes what
10 -- yes, there it is.

11 And then instead of amending the bylaws
12 with language, I would just suggest that we refer in
13 Section 4.1 to the government document that we will
14 be able to cite, once we have that citation, and take
15 out all the other language about financial conflict.

16 CHAIRMAN PALESTRO: Regarding a conflict
17 of interest, is that acceptable to legal? Ms. Weil's
18 proposal, does that make sense?

19 MS. HOUSEMAN: It does but to confirm, I
20 would need to go back to the division in the Office
21 of the General Counsel that specializes in advising
22 on the government ethics rules and run it by them.

23 CHAIRMAN PALESTRO: Thank you.

24 Any more, comments, questions, discussion
25 on these two topics?

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1 All right, can I have a motion to approve
2 the amended report? Dr. Dilsizian.

3 Second?

4 (No audible response.)

5 CHAIRMAN PALESTRO: Any further
6 discussion?

7 All in favor?

8 Any opposed?

9 Any abstentions?

10 Okay and Ms. Holiday, I would like to go
11 on the record as indicating that my abstention was not
12 or should not be considered a vote against or a negative
13 vote but rather, as I stated when I formed the
14 subcommittee, abstention because of the obvious
15 conflict of interest.

16 I would like to thank the subcommittee for
17 your work on this because I found this a very vexing
18 issue, as the chair, having been so intimately involved
19 in the Training and Experience Subcommittee and then
20 being told that I had to give it up and not being able
21 to find a hard and fast reason as to why documented.
22 It was difficult.

23 So I think you have cleared, at least for
24 me and hopefully, for future chairs what potentially
25 can become an issue and I thank you very much for that.

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1 And I think your rationale for doing so regarding
2 expertise was exactly something that had come up in
3 my mind when Dr. Metter and I had talked about it.

4 In your report, you alluded to another
5 issue, another problem that we sometimes face and that
6 is institutional memory, going back and trying to
7 retrieve documents and so forth in the past. There
8 is no good way to do it and we ran into that numerous
9 times continually, when we tried to sort through how
10 the 700 hours for training and experience was arrived
11 at.

12 Having said that, I think it is reasonable
13 to form a subcommittee with a charge for improving or
14 at least attempting to improve the ACMUI's
15 institutional memory.

16 MEMBER WEIL: I believe that the website
17 that has been established for ACMUI subcommittee
18 charges and reports will ameliorate that situation
19 going forward. Do you think Sophie?

20 CHAIRMAN PALESTRO: The answer is I don't
21 know but one of the issues that comes up is, and you
22 noted in your report, that while there are transcripts
23 of the meeting minutes, they aren't categorized or there
24 is no cross-referencing by subject.

25 So while I think the website improves

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1 things, I'm not sure that it solves all of the issues.

2 And the truth of the matter is, the subcommittee can
3 come back and say this is as good as it gets; there
4 are no additional recommendations. I think it behooves
5 us to look at it.

6 That's my only thought. And maybe this
7 is where it ends.

8 So with that in mind, I am going to ask
9 Dr. Schleipman to chair this committee. I am going
10 to ask Ms. Shober to be a part of that; Ms. Weil, for
11 whatever time you have left, I would like to have you
12 on that; Dr. Ennis; and Dr. O'Hara because you work
13 for another federal agency and you may have some unique
14 insights into institutional memory.

15 All right, staff resource? Okay, Ms.
16 Kellee Jamerson.

17 All right and then finally, before we move
18 on to the open forum, if I could just ask the
19 subcommittee chairs, when you are presenting your
20 reports, be they slides or full reports, please make
21 sure to include the name of the staff resource on that
22 introductory slide.

23 All right, the next item on the agenda is
24 the open forum; topics of interest previously
25 identified or maybe not identified. Anybody have

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1 anything that they would like to bring up?

2 Ms. Dimmick.

3 MS. DIMMICK: Thank you. Lisa Dimmick,
4 Medical Team Leader.

5 It is more or less just a follow-up to a
6 previously discussed item and it is about the Medical
7 Event Subcommittee's recommendation for an information
8 notice. It was discussed during the Commission
9 briefing and there wasn't really an opportunity for
10 staff to provide any input to that. But I did want
11 to add that that information notice is on the Medical
12 Team's work plan for FY19. So we do plan to have at
13 least the IN drafted and hopefully starting in
14 concurrence by the end of fiscal year '19. So that
15 would be the end of September.

16 So in anticipation that there should be
17 an information notice drafted in September.

18 CHAIRMAN PALESTRO: Thank you.

19 Dr. O'Hara, a little while ago, you and
20 I were talking and I suggested that you bring up your
21 observations at the open forum. And so could I ask
22 you to expand on it?

23 MEMBER O'HARA: Yes, yesterday we were
24 discussing the National Nuclear Safety Association's
25 plans for isotope use in the United States. And I sit

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1 on a couple of their committees. So I have some
2 knowledge of what is going on. There is someone at
3 NRC who sits on that committee as well, because I have
4 heard her speak before.

5 But what I heard was concern from Ms. Martin
6 and others that we will lose the use of specific
7 isotopes. And we all know that the isotope that is
8 tops on the hit list is cesium but people were mentioning
9 other isotopes. So what I suggested to Dr. Palestro
10 was that we invite the NNSA here to tell us about their
11 -- where they are, where they are going and so that
12 we have the option to understand where they are going
13 and begin to push back, if they are planning on getting
14 rid of iridium or something like that.

15 CHAIRMAN PALESTRO: Ms. Holiday, before
16 I open the discussion to the group, are there
17 restrictions on having invited speakers?

18 MS. HOLIDAY: No, absolutely not. If you
19 guys will remember, a couple of years ago when NNSA
20 was rolling out their GTRI program -- am I saying that
21 right -- G-T-R-I program, NNSA came and gave
22 presentations on that. So they are not -- they are
23 a familiar face here.

24 So if this is something that the committee
25 wishes to hear about, then we will make the contact

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1 with NNSA.

2 CHAIRMAN PALESTRO: Comments, questions?

3 MR. EINBERG: Yes, if Dr. O'Hara has a
4 contact person, that would help facilitate us making
5 that arrangement.

6 CHAIRMAN PALESTRO: Any other comments or
7 questions?

8 Ms. Martin.

9 MEMBER MARTIN: I would just speak in
10 support of that. I think it would be wonderful for
11 this committee to know what the plans are as far as
12 use of medical isotopes. Are the restrictions
13 potential restrictions on the use of certain isotopes?

14 CHAIRMAN PALESTRO: Dr. Ennis.

15 MEMBER ENNIS: Yes, I would encourage us
16 to embrace this topic. I have a lot of concerns about
17 and have heard about grumblings before. I kind of
18 alluded to it in the Commission briefing. And whatever
19 we can do to kind of engage them in dialogue, perhaps
20 even suggesting they have their own ACMUI might be good.

21 So, let's start the conversation.

22 CHAIRMAN PALESTRO: Any other comments or
23 questions? Attendees in the room? Bridge line?

24 All right, Dr. O'Hara, can I ask you to
25 put this in the form of a motion?

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1 MEMBER O'HARA: I move that the ACMUI
2 contact the NNSA and ask them to come to a meeting,
3 to one of our meetings and review their plans for isotope
4 utilization in the United States.

5 CHAIRMAN PALESTRO: Second?

6 Dr. Schleipman.

7 Any further discussion?

8 All in favor?

9 Any opposed?

10 All right, thank you very much for that,
11 Dr. O'Hara.

12 And I think, recognizing that there are
13 a lot of things that need to be accomplished at these
14 meetings and so forth, that going forward we need to
15 consider having outside individuals from different
16 groups appear more often. It strikes me that over the
17 course of my eight years, most of the time the outside
18 speakers have been vendors.

19 MS. HOLIDAY: Dr. Palestro and Dr. O'Hara,
20 if I may, I know that the committee just voted
21 unanimously for this recommendation.

22 Point of clarification: I think the
23 committee means the NRC staff will reach out, not the
24 ACMUI will reach out.

25 CHAIRMAN PALESTRO: Thank you.

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1 MS. HOLIDAY: Thank you.

2 CHAIRMAN PALESTRO: Any other items for
3 the open forum?

4 All right, hearing none, we will move on
5 to the administrative closing and I will turn this over
6 to Ms. Jamerson.

7 MS. JAMERSON: So I provided a meeting
8 Doodle poll to all of the members of the committee for
9 tentative dates for the 2019 fall ACMUI meeting.

10 Again, our fall meeting occurs in either
11 September or October and, as it's been mentioned, Dr.
12 Palestro's term ends September 21st. So I wanted to
13 schedule the meeting prior to the end of his term.

14 Considering this, the selection of dates
15 for the fall meeting was rather limited. And so the
16 options that received the most votes were for September
17 9th and 10th; September 10th and 11th; and September
18 11th and 12th.

19 So from these dates, from these options,
20 is there a preference of the committee for the fall
21 meeting?

22 MEMBER MARTIN: I just realized I can't
23 make any of those dates. I'm going to be out of the
24 country. I'm sorry.

25 MS. JAMERSON: So I will clarify that for

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1 September 9th, Mr. Green and Ms. Martin have conflicts.

2 For September 10th, again, Mr. Green and Ms. Martin
3 have conflicts. For September 11th, Ms. Martin is also
4 away. And for September 12th, Dr. Dilsizian and Ms.
5 Martin have conflicts.

6 MEMBER DILSIZIAN: I could potentially
7 make the 12th.

8 MS. JAMERSON: Okay.

9 MEMBER GREEN: I could potentially make
10 the 10th. I'd just have to do some travel arrangements.

11 MS. JAMERSON: So I propose from this that
12 September 11th and 12th as the first option and, for
13 the backup dates, would be September 10th and 11th.

14 Is that okay with the committee?

15 CHAIRMAN PALESTRO: Works for me.

16 Other members? Ms. Martin.

17 MEMBER MARTIN: Point of clarification.
18 Since you gave me the subcommittee that is supposed
19 to report back at this meeting, do you want me to try
20 and get the report meeting and have some other member
21 of the committee give it or hold the subcommittee report
22 until the spring meeting?

23 CHAIRMAN PALESTRO: There are a couple of
24 ways it could be done. One, is to prepare the report
25 and have someone designated from your subcommittee.

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1 That might be the easiest.

2 MEMBER MARTIN: Okay.

3 CHAIRMAN PALESTRO: Alternatively, we
4 could hold a telephone conference meeting over the
5 summer.

6 MEMBER MARTIN: Okay.

7 CHAIRMAN PALESTRO: All right. I would
8 rather not delay it beyond the fall meeting.

9 MS. JAMERSON: Okay.

10 CHAIRMAN PALESTRO: I'm sorry, Ms.
11 Jamerson, for me could you repeat the days?

12 MS. JAMERSON: Yes, so our fall meeting
13 will be September 11th and 12th and our backup date
14 will be September 10th and 11th.

15 CHAIRMAN PALESTRO: Thank you.

16 MS. JAMERSON: So the other portion of our
17 administrative closing is where we review any of the
18 new recommendations or actions that have occurred
19 during the course of this two-day meeting.

20 First, the ACMUI endorsed the Yttrium-90
21 Microsphere Brachytherapy Licensing Guidance, Revision
22 10 Subcommittee report and the recommendations therein
23 with the caveat that the term drug be changed to device.

24 Do you agree?

25 CHAIRMAN PALESTRO: Yes.

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1 MS. JAMERSON: Okay. Secondly, Dr.
2 Palestro formed a Subcommittee to Reevaluate the 1980
3 Infiltration Decision and report to the committee at
4 the fall 2019 meeting with any recommendations. The
5 subcommittee members include Dr. Dilsizian, Mr. Green,
6 Ms. Martin as the chair, Mr. Sheetz, Ms. Shober, and
7 Ms. Weil. And the staff resource for this is Maryann
8 Ayoade.

9 Do you agree?

10 CHAIRMAN PALESTRO: Yes.

11 MS. JAMERSON: For item 5, the ACMUI
12 endorsed the Germanium-68/Gallium-68 Generator
13 Licensing Guidance, Revision 1 Subcommittee report and
14 the recommendations therein.

15 Do you agree?

16 CHAIRMAN PALESTRO: Yes.

17 Question: Can this item now be closed or
18 not? No. Can you explain why, Ms. Holiday, again?

19 MS. HOLIDAY: Sure. So at the present
20 time, this is ACMUI providing its recommendations for
21 revisions to the Germanium/Gallium-68 Generator
22 Licensing Guidance. So that is being provided to the
23 NRC staff and the working group, Agreement State Working
24 Group for them to disposition and, if they agree, make
25 changes to the guidance with respect to the

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1 recommendations that the subcommittee provided.

2 And then after the guidance has been
3 finalized, a memorandum should be distributed to the
4 ACMUI to inform you of how they dispositioned your
5 recommendations.

6 So this will stay open until 1) the guidance
7 comes out; and 2) the memorandum is provided to the
8 ACMUI.

9 CHAIRMAN PALESTRO: Thank you.

10 MR. EINBERG: Excuse me, Dr. Palestro.

11 Sophie, just to lessen your bureaucracy
12 around issuing a memorandum, once we issue the licensing
13 guidance, is there any reason that this couldn't be
14 closed, rather than waiting for a memorandum?

15 MS. HOLIDAY: Mr. Einberg, this was a
16 recommendation, though not formally captured in the
17 recommendation chart, that came from the ACMUI several
18 years ago. And they requested a memorandum so that
19 they could know exactly how the recommendations were
20 dispositioned. And because of that, they requested
21 that these items remain open until that memorandum comes
22 to them.

23 MR. EINBERG: I see. Okay, thank you.

24 MS. HOLIDAY: So in my haste to put this
25 up, I did not put any edits that the committee just

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1 voted on for the Bylaws Subcommittee. So I am going
2 to have to read from my sticky note. The language you
3 see on this screen is not what I am reading.

4 So item 6 is that the ACMUI endorsed the
5 ACMUI Bylaws Subcommittee report with the caveat that
6 the report be amended to remove the phrase in these
7 instances and to add language about the ACMUI chairman
8 will serve on the subcommittee at the subcommittee's
9 discretion.

10 Additionally, the report will be amended
11 in Section 4.1 to reference the OGE reference that will
12 be provided by the Office of General Counsel.

13 This was unanimously approved by the ACMUI.

14 The motion was put forth by Dr. Dilsizian and seconded
15 by Ms. Martin. However, it should be noted that Dr.
16 Palestro abstained from the vote so that his vote would
17 not present as a conflict of interest.

18 Did I accurately capture the committee's
19 recommendations?

20 Yes, Dr. Schleipman.

21 MEMBER SCHLEIPMAN: I think you missed
22 that we were removing the prior addition of spelling
23 out the financial conflicts of interest.

24 MS. HOLIDAY: Yes, you are absolutely
25 right. Yes, you are correct.

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1 So with that, does the committee agree?
2 Okay.

3 Another item not captured on here was that
4 the NRC staff agreed to add language specifically about
5 the conflict of interests in our opening remarks at
6 every ACMUI meeting.

7 Does the committee agree? Thank you.

8 Another item not captured on here -- I'm
9 sorry. Oh.

10 Another item not captured on here is that
11 the ACMUI recommended that the NRC staff invite the
12 NNSA to present at the fall 2019 ACMUI meeting to review
13 its plans for isotope utilization in the United States.

14 Does the ACMUI agree?

15 CHAIRMAN PALESTRO: Yes.

16 MS. HOLIDAY: Thank you and I will turn
17 it back to you, Ms. Jamerson.

18 MR. EINBERG: Ms. Jamerson and Ms.
19 Holiday, can we add a column or can we have an action
20 item to add a column to this table with a target date
21 for completion?

22 MS. HOLIDAY: Yes. Does that need to be
23 made a motion or captured?

24 MR. EINBERG: I think we discussed it or
25 the ACMUI members discussed it. We committed to that.

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1 So I'm not sure if there needs to be a motion or not
2 but I think that would be a useful item for tracking
3 these items.

4 CHAIRMAN PALESTRO: Rather than debating
5 whether we need a motion, why don't we just make one?
6 This way, it is definitive.

7 So can we have a motion to add an extra
8 column on our recommendations and action items that
9 will include the anticipated date of completion? Is
10 that correct, sir?

11 MR. EINBERG: That's correct.

12 CHAIRMAN PALESTRO: Okay.

13 Mr. Ouhib?

14 MEMBER OUHIB: Yes, I make the motion.

15 CHAIRMAN PALESTRO: Second?

16 (No audible response.)

17 CHAIRMAN PALESTRO: Any discussion?

18 All in favor?

19 All right, any opposed?

20 Thank you.

21 MS. HOLIDAY: So point of clarification.

22 Is this a target date of completion for NRC staff
23 action?

24 MR. EINBERG: Yes.

25 MS. HOLIDAY: Thank you. So, for the

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1 record.

2 MS. JAMERSON: Also not listed on this is
3 Dr. Palestro formed a new subcommittee. The charge:
4 for improving ACMUI's institutional memory.

5 Dr. Schleipman is the chair. Other
6 subcommittee members include Dr. Schleipman as the
7 chair, Ms. Shober, Ms. Weil, Dr. Ennis, Dr. O'Hara,
8 and Kellee Jamerson as the NRC staff resource.

9 Does the ACMUI agree?

10 CHAIRMAN PALESTRO: Yes.

11 MS. JAMERSON: And the last item is the
12 ACMUI tentatively scheduled its fall 2019 meeting for
13 September 11th and 12th, 2019. The alternate date is
14 September 10th and 11th, 2019.

15 Does the ACMUI agree?

16 Okay, this concludes my administrative
17 closing.

18 MEMBER OUHIB: Kellee, when do you
19 anticipate to have a final date for the meeting between
20 the two?

21 MS. JAMERSON: By next month.

22 CHAIRMAN PALESTRO: All right. Are there
23 any other items, Committee? No.

24 Just before we adjourn, just to remind
25 especially the new members, and obviously to help a

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1 couple of you with the hotel rooms, but I would suggest
2 that you make your reservations ASAP. I learned the
3 hard way for my first meeting and since then, as soon
4 as this meeting ends, I go and make my reservations
5 for both meeting dates and then cancel the one that
6 we're not going to use.

7 So all right, with that, the meeting
8 concludes. It is adjourned. I thank you all and we
9 will see you again in September.

10 (Whereupon, the above-entitled matter went
11 off the record at 2:13 p.m.)
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