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	Medical Uses of Isotopes (ACMUI), Day 2

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2019 MEETING

+ + + + +

THURSDAY,

APRIL 4, 2019

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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

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

ROBERT MACDOUGALL, NMSS/DRM/MRPB

SCOTT MOORE, NMSS, Deputy Director

JANICE NGUYEN, R-I/DNMS/MLAB

DENNIS O'DOWD, R-III/DNMS/MIB

PATRICIA PELKE, R-III/DNMS/MLB

DAVID PELTON, R-III/DNMS

ALEXA SIERACKI, NMSS/DRM/MRPB

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)

MARY BURKHART, Illinois Emergency Management Agency

ASHLEY COCKERHAM, SirTex Medical

JASON COLLIER, Lehigh Valley Health Network

WHITNEY COX, Illinois Emergency Management

Agency

WILLIE (JACK) CRAWFORD, Virginia Office of Radiological Health LYNNE A. FAIROBENT, Unaffiliated 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 Office KANABROCKI, Virginia of PAUL Radiological Health HEATHER KARMANSKY, SirTex Medical RALPH LIETO, St. Joseph Mercy Health Center JEFF MASON, Virginia Office of Radiological Health STEVE MATTMULLER, Kettering Health ANDREW McKUSICK, Unknown ASHLEY MISHOE, University of California, San Francisco JOSHUA MYERS, Pennsylvania Department of Environmental Protection SCOTT NEMMERS, U.S. Air Force MICHAEL PETERS, American College of Radiology BRAD PRICE, GE Healthcare

EUGENIO SILVESTRINI, Northwell Health

LAKSHMI SIVASUBRAMANIAN, University of Massachusetts Medical School

DIANA THOMPSON, University of Illinois at Chicago

WILLIAM WHITE, Rush University Medical Center NEIL WHITESIDE, Yale New Haven Hospital MATTHEW WILLIAMS, Georgetown University MATTHEW WILLIAMSON, Memorial Sloan Kettering Cancer Center

ROBERT WILSON, University of Tennessee Health Science Center

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1	PROCEEDINGS
2	(8:31 a.m.)
3	CHAIRMAN PALESTRO: All right, good
4	morning. We're getting ready to start Day 2 of the
5	ACMUI Spring 2019 meeting. And the first session on
6	today's agenda is the ACMUI reporting structure and it
7	will be reported by Ms. Kellee Jamerson.
8	MS. JAMERSON: I will be giving the annual
9	presentation on the committee's reporting structure.
10	So our outline for today includes the
11	current reporting structure. This presentation will
12	serve as your annual review. We will discuss how
13	often we conduct our meetings and then open it up for
14	a discussion.
15	This chart shows the organizational
16	structure within the NRC from the Division of
17	Materials Safety, Security, State, and Tribal
18	Programs, up to the Commission.
19	The ACMUI reports directly to Ms. Andrea
20	Kock, Director of the Division of Materials Safety,
21	Security, State and Tribal Programs.
22	My branch, the Medical Safety and Events
23	Assessment Branch also reports to Ms. Kock.
24	While the ACMUI does not report to the
25	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
5	Kevin Williams, our Deputy Division Director, this
6	does not preclude you from communicating or
7	interacting with the Director of our office, the
8	Office of Nuclear Material Safety and Safeguards or
9	our Executive Director of Operations, or to the
10	Commission.
11	In September 2012, as indicated on the old
12	business chart, the ACMUI recommended to have an
13	annual review of the reporting structure open
14	indefinitely. In May 2014, the Bylaws Subcommittee at
15	that time presented the committee with the option to
16	continue reporting to NMSS or directly to the
17	Commission.
18	The subcommittee report stated that the
19	working relationship between the NRC and the ACMUI
20	remains excellent. The reporting structure, through
21	NRC staff, continues to function effectively and the
22	associated logistical overhead associated with direct
23	reporting to the Commission did not and does not now
24	justify any change in the ACMUI's reporting structure.
25	This presentation marks the ninth review
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1	of the reporting structure.
2	Currently, the ACMUI holds two meetings at
3	NRC Headquarters each year. The spring meeting takes
4	place in either March or April and the fall meeting
5	occurs in September or October.
6	The ACMUI also has approximately two to
7	three teleconferences per year, as needed. We have
8	already conducted one teleconference on February 26th
9	and we will likely have two more this summer to
10	receive the committee's comments on the staff's draft
11	commission paper related to the training and
12	experience requirements and the draft revisions to
13	Regulatory Guide 8.39.
14	As you can see, the number of
15	teleconferences varies, depending on the needs of the
16	committee, as well as the needs of the staff and the
17	Commission.
18	At this point, I would like to open it up
19	for discussion to the committee and, for your
20	consideration, these questions for you to discuss.
21	Do you still agree with the current
22	reporting structure where the ACMUI reports to the
23	MSST management or would you rather report directly to
24	the Commission?
25	Are you satisfied with the frequency of
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1	the meetings; that is, two in-person meetings here at
2	NRC Headquarters, with as-needed teleconferences?
3	And lastly, are there any other changes
4	that you would like to see?
5	I will turn it over to Dr. Palestro.
6	CHAIRMAN PALESTRO: Dr. Metter?
7	VICE CHAIRMAN METTER: Thank you, Kellee.
8	Do you mind going back to that chart? You
9	have the directors and I know you probably know who
10	they are but can you give us their names so we know
11	can identify a name with the position?
12	MS. JAMERSON: Sure. John Lubinski is the
13	Director of NMSS, whom you met yesterday.
14	The Director of MSST is Andrea Kock. She
15	could not attend. Our Deputy Director is here, Kevin
16	Williams.
17	Our Executive Director of Operations is
18	Margaret Doane.
19	VICE CHAIRMAN METTER: Okay, thank you.
20	CHAIRMAN PALESTRO: Other
21	questions/comments?
22	I have a question regarding the reporting
23	structure. The way it is designed, we report up
24	through various levels. What would be the advantages
25	or disadvantages of changing that reporting structure?
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1	Because I certainly have no idea.
2	MS. HOLIDAY: Okay, so this is Sophie
3	Holiday, for those listening on the webinar.
4	So currently we have three Federal
5	Advisory Committees or FACA Committees here at the
6	NRC. The one that everyone is most familiar with,
7	aside from our committee here, is ACRS, which is the
8	Advisory Committee for Reactor Safeguards. And that
9	is the only FACA committee here at NRC that reports
10	directly to the Commission.
11	So because they report directly to the
12	Commission, they have their own office, if you will, a
13	dedicated staff that helps them because they generate
14	a lot of letter reports, as I understand it. They
15	meet here at headquarters at least ten times a year
16	for in-person meetings and also subcommittee meetings
17	in-between or also during those ten meeting times a
18	year.
19	Honestly, reporting directly to the
20	Commission versus reporting through the division,
21	through our division, MSST, is not necessarily very
22	different in terms of if you feel the ACMUI wants to
23	have access to the Commission, the dotted lines from
24	ACMUI to the Director of NMSS, to EDO, or to the
25	Commission simply means that we have an open door
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Maybe a couple of the members on the committee may remember at one time our previous chairman, I believe it was Dr. Thomadsen, scheduled drop-in meetings with the Commission, particularly, he held them the day before the ACMUI meeting when it was convenient because he was in town at that time. At any other time, any member here on the ACMUI can meeting with request to have а any of our commissioners, or the EDO, or any of our levels of management.

In terms of the disadvantages, I think one of the reasons, as I recall from the paper that Kellee referenced before, the reason that the committee had previously stated that they wanted to retain the current reporting structure, that is, to report 17 through our division and our office, is that it would be less frequent meetings, not to say that you would 18 19 not be as visible to the Commission but you would not be as demanded of, if that makes sense. 20

21 Because a lot of our rules and our 22 regulations here at the NRC are very much so centered around nuclear reactors, that is why that particular 23 frequently as they do, 24 FACA Committee meets as 25 produces as many reports as they do. Their reports do

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1	go straight to the Commission; whereas, for the
2	committee, any subcommittee report that you submit and
3	it ties into any policy changes that the NRC staff is
4	pursuing, we append your unfettered comments, which is
5	your report to our SECY papers, to our memorandums, to
6	our Commissioner Assistant notes, so that they are
7	able to hear verbatim what the committee has said.
8	Hopefully, that answered your question.
9	CHAIRMAN PALESTRO: Yes, it does. Thank
10	you.
11	MS. HOLIDAY: Thank you.
12	CHAIRMAN PALESTRO: Any other questions or
13	comments? Ms. Weil.
14	MEMBER WEIL: As the historian, I guess,
15	on this committee, when I first came on there was some
16	question about why an annual review. Why can't we
17	just settle on how we function? And the reason I was
18	given, and this occurred before my time, before
19	Kellee, before Sophie, before Ashley, there was some
20	dissatisfaction on the ACMUI with the staff support
21	that we had.
22	And so there was a decision made to
23	annually review whether we are content with the
24	support that the committee is given and whether we
25	want to continue in our current organizational
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1	structure.
2	I just thought I would offer that
3	perspective.
4	CHAIRMAN PALESTRO: Thank you.
5	Any other comments or questions?
6	Is there a general consensus that we are
7	content with the structure, recognizing that many of
8	you are new on the committee and haven't had a lot of
9	experience with it?
10	Dr. Ennis.
11	MEMBER ENNIS: Just my personal opinion, I
12	am content. Actually, overall, content in this part
13	of my life.
14	(Laughter.)
15	MEMBER ENNIS: You know over the years
16	that I have been on, the NRC staff has been fabulous.
17	I do have, as I expressed a little bit
18	yesterday, though, a little bit of a concern about
19	whether they have enough support. I don't know if,
20	personally, I am at a point where I feel like we need
21	to do something about it because there have been some
22	additions with Kellee and a new position. So
23	personally, I may be willing to kind of give it
24	another six months to a year. But even with that
25	issue, I don't think that is so much about structure
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1	but it may be about whether we need to have a meeting
2	directly with someone higher up on the chain.
3	CHAIRMAN PALESTRO: Zoubir.
4	MEMBER OUHIB: I would just like to echo
5	what Dr. Ennis just said. I really believe that there
6	is still need for more support for the staff in order
7	for the ACMUI to actually accomplish what we want to
8	accomplish. There are other things that we probably
9	could tackle but I think knowing that the staffing is
10	probably not ideal, we tend to back up rather than try
11	to push.
12	CHAIRMAN PALESTRO: Thank you.
13	Any other comments?
14	Mr. Einberg?
15	MR. EINBERG: This is Chris Einberg.
16	In regards to the staff support, in the
17	past year or so, there have been challenges with the
18	backfilling for some people that were out. I think we
19	are righting the ship in that regard. And so we are
20	putting priority and trying to we are going to put
21	an additional priority on closing these open items.
22	We heard you yesterday and we will make that a
23	priority to close some of these open items.
24	And so if there is a need for additional
25	staff support, management here does support getting
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1	additional resources. We have the flexibility to try
2	to bring on people on rotations and details to help
3	close some of these action items. So we will work
4	those issues to try to close those action items and
5	get the support you need.
6	Other than the open items, is there
7	anything else that you feel that there is additional
8	support needed?
9	CHAIRMAN PALESTRO: Dr. Ennis?
10	MEMBER ENNIS: I don't have a specific
11	thing but, as Mr. Ouhib just mentioned, we do, or at
12	least I feel like we function a little bit with a
13	cloud over our heads well, don't ask for too much
14	or don't try and do too much because the staff can't
15	do that. That's not really an ideal way for ACMUI to
16	function.
17	MR. EINBERG: I'm not sure I understood
18	the comment. Perhaps you can rephrase it.
19	The staff is asking you not to do too
20	much?
21	MEMBER ENNIS: No, it's just that we get a
22	feeling. Like because things take a long time and
23	occasionally, there will be comments like within our -
24	- we will tackle that within our resources.
25	Now of course, we understand there is a
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1	budget, and a federal deficit, and all of that but it
2	feels a little bit like, in such a big organization,
3	to have such limited resources isn't a good balance.
4	And it feels just like it is something that we have to
5	always be aware of; you can only do a little bit.
6	MR. EINBERG: Okay.
7	MR. WILLIAMS: So also, if I may, this is
8	Kevin Williams, the Deputy Director.
9	So those types of activities, and I know I
10	can speak on behalf of Andrea, she wants to be aware
11	of those types of activities. We are constantly
12	looking at our workload, and analyzing it to see how
13	best to support all of the things that we are doing.
14	I certainly wouldn't want you to feel as
15	though there is a cloud or we are limited in terms of
16	what we can do. So, we would like you to bring those
17	types of things up to us. You can work through
18	Kellee, and Chris, and so forth but we will address
19	what we can but we can't necessarily address what we
20	don't know.
21	And so I appreciate your candor and I
22	would ask that you continue to push and let us know
23	where the challenges are because we will identify
24	those.
25	I think yesterday one of the things we
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1	talked about was the plans and the activities that we
2	have committed to. Chris and I talked offline and
3	that was one of the things that we said we wanted to
4	make sure we have a plan with a milestone and
5	schedule. So that is one thing that we know that is
6	tangible and that we can actually address.
7	So I would look forward to continue
8	engaging and letting us know where there are areas
9	that we can enhance the program.
10	MEMBER ENNIS: That's great. I appreciate
11	it.
12	Just to be clear, the individuals with
13	whom we work are fabulous. It is not meant at all as
14	a criticism of the current staff that we have.
15	MR. WILLIAMS: No, I know that.
16	CHAIRMAN PALESTRO: Dr. Metter.
17	VICE CHAIRMAN METTER: Thank you, Kellee.
18	And this may be a very minute question but
19	you know when we talk to NRC staff and then you say
20	you have to clear it with management, who is that?
21	Oh, okay. Thank you, Kevin. Okay.
22	CHAIRMAN PALESTRO: Zoubir.
23	MEMBER OUHIB: Just to echo Dr. Ennis
24	again is that I just want to make sure this is clear.
25	This is not a wave that is coming from the staff, in
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1	all honesty. Because again, they are great, very
2	accommodating and will do whatever they can. It is
3	just more like us, at least from my point of view, us
4	looking at the whole program and try to see well, yes,
5	we could look into this, we could look into this but
6	can we really do it? Listen to what they are dealing
7	with and what they have to meet, and so on and so
8	forth. So we tend to well, let's just wait a little
9	bit and then maybe we can address this or we can
10	address that.
11	I mean ideas come and go and we are like
12	maybe next year, whatever. So I just want to make
13	sure it is not coming from them. It is us looking at
14	it.
15	MR. WILLIAMS: Yes, so hows I would
16	respond to that is I want to go on the record as
17	saying I think Sophie and Kellee do a great job. They
18	are amazing and they work diligently to make sure that
19	this program runs at a high-functioning level.
20	So I would want to reiterate is the fact
21	that the whole purpose of this is to take that
22	critical look at the program, the processes, and to
23	say hey, is there something that we can do better. We
24	wouldn't want you to feel as though you were limited.
25	So there are things that you are thinking about.
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1	Let's talk about those things because in talking
2	through them, we can develop plans. We can look at it
3	and see if there is a way to do it.
4	We don't necessarily have to move at a
5	snail's pace but if you are bringing those issues up
6	to us, we are aware of what they are and we can take
7	some sort of action.
8	CHAIRMAN PALESTRO: Any other comments or
9	questions from the committee? Mr. Fuller.
10	MR. FULLER: Yes, this is Mike Fuller and
11	I am the Director of the Virginia Radioactive
12	Materials Program but I have some experience.
13	So again, to bring a little bit more of an
14	historical perspective, I guess, one thing that hasn't
15	been mentioned and I know everybody knows this, but
16	just so that the new folks on the ACMUI are also
17	aware, there is another big difference between the
18	ACRS and the ACMUI.
19	The ACRS reports directly to the
20	Commission, yes, and they have certain areas of
21	expertise. Each of the members are you know highly
22	specialized in what they do. But the NRC staff has,
23	possesses all of those skills, all of that knowledge,
24	and that experience, and so forth, the same sort of
25	specialists. So it works for the ACRS to report
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	21
1	directly to the Commission because the staff has the
2	exact same expertise, or at least very similar
3	expertise.
4	What is different and one of the reasons
5	why the ACMUI reports to staff is because this
6	committee comprises and has certain technical,
7	medical, clinical expertise that the staff does not
8	have. So this committee advises the staff because the
9	staff does not have what you have as far as experience
10	and expertise.
11	So that is another reason why this
12	committee reports and supports the staff, as opposed
13	to the Commission, because if you reported directly to
14	the Commission, the Commission would not have another
15	so with the ACRS, the Commission can hear from the
16	Advisory Committee can also hear from staff and get
17	maybe two perspectives, or maybe a different nuanced
18	perspective. Whereas, if you reported directly to the
19	Commission, the staff has nothing to offer.
20	So anyway, I just thought I would add
21	that. Like I said, I think that is sort of in the
22	back of everybody's mind but it just didn't come up in
23	this discussion and for the benefit of the newer
24	members on the ACMUI.
25	So thank you.
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1	CHAIRMAN PALESTRO: Thank you.
2	Any other comments or questions?
3	One item that I think comes up
4	periodically is the number of face-to-face meetings
5	per year. So I would ask if the committee has any
6	thoughts on that.
7	As you all know, we meet twice a year;
8	fall and spring. And the discussion has come up
9	periodically as to whether or not a third or fourth
10	face-to-face meeting could potentially be useful or
11	necessary. So I am just putting that out for a
12	discussion and comment.
13	Dr. Ennis.
14	MEMBER ENNIS: It looks like there are so
15	many new members who can't really offer an opinion on
16	that so, I will speak up that I think it is an
17	appropriate balance. It feels to me twice a year is
18	good is the right amount.
19	CHAIRMAN PALESTRO: Yes, this question
20	comes up periodically at these annual reviews and it
21	has generally been a consistent response that while an
22	additional face-to-face meeting or two might be
23	desirable, the logistics involved and so forth far
24	outweigh any benefits. And that at least at the
25	present time, and again, we have the opportunity to
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	23
1	review it annually.
2	The two face-to-face meetings,
3	supplemented with a sufficient number of telephone
4	conferences during the year are sufficient to complete
5	our business.
6	Any other comments? Zoubir.
7	MEMBER OUHIB: Yes, I think biannual is
8	probably sufficient. However, with the emerging
9	technology and things that we are all going to be
10	dealing with in the very near future, perhaps to sort
11	of not necessarily say okay, let's do it three times
12	or something like that, but be flexible and have the
13	ability to add another face-to-face meeting to sort of
14	deal with urgent matters that will come along.
15	CHAIRMAN PALESTRO: All right, thank you
16	for that.
17	Maryann.
18	MS. AYOADE: Yes, Maryann, NRC member.
19	I just wanted to add that we do have
20	opportunities where if the ACMUI members feel that
21	they need additional face-to-face, we can try to
22	accommodate that.
23	For example, last year with the T&E
24	Subcommittee, Dr. Metter asked for a face-to-face
25	working day with the subcommittee a day before the
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1	meeting. And we were able to accommodate that. And
2	that worked with people's schedules because they
3	didn't have to plan a separate visit outside of the
4	two annual or the two times you guys come in in the
5	year.
6	And I don't know, historically, if,
7	Sophie, this has been done before but we were able to
8	accommodate that. So that might be something that
9	some of the members may want to consider if they think
10	a face-to-face meeting would benefit their
11	subcommittees in moving forward.
12	MS. HOLIDAY: Hi, Maryann. Thank you for
13	that input.
14	And Maryann is quite correct. We did do
15	that last year for the T&E Subcommittee. For the time
16	that I have been with the committee, has been roughly,
17	oh, gosh, nine years, I can only remember maybe one or
18	two other instances where we brought members in a day
19	before the meeting. And that was really more so to do
20	the Commission dry run because, at that time, the
21	Commission meeting was on Day 1 of the ACMUI meeting
22	versus Day 2.
23	That being said, you know just like
24	Maryann said, if this is something that the committee
25	desires, subject to budget availability because travel
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1	does cost quite a bit of money and our members are
2	scattered across the country, you know we would do our
3	best to support you in those efforts.
4	With respect to what Mr. Ouhib said
5	regarding emerging medical technologies and I believe
6	the word you used was urgent, I personally find that
7	with urgent matters, an ad hoc teleconference is a
8	better approach in terms of it allows you a little bit
9	more flexibility, members are able to set aside two
10	you know one to three hours. I think our longest
11	teleconference has been three hours for a given topic
12	or two topics.
13	The reason that we have these in-person
14	meetings twice a year is because it covers several
15	different topics. So unless, for example, the
16	emerging medical technologies, if that had evolved
17	into numerous agenda topics where it could cover a day
18	or two, I think NRC would be very supportive of that.
19	But like we said, we are flexible. It
20	hasn't happened yet but if it does come to that point,
21	I don't see an objection.
22	I see nods from the management.
23	CHAIRMAN PALESTRO: Any other comments or
24	questions? Dr. Dilsizian.
25	MEMBER DILSIZIAN: Thank you.
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1	I guess my observation over the last three
2	or four years now, is that I don't see any issue of
3	ACMUI coming up with an agenda and recommendations.
4	The reason I think we don't need more than two is
5	because a lot of our recommendations don't actually
6	become reality for several years.
7	So I don't understand what the urgency
8	would be because I feel like I have been on this
9	committee, this is my fifth year, a lot of things that
10	we have discussed, that we have proposed, or
11	recommended, we are still very active and nothing is
12	happening. So to me, the urgency of doing more
13	meetings would be if those actually become actionable
14	items.
15	So we can talk all we want to. We can
16	present all these nice ideas but I think that there
17	doesn't seem to be urgency from the NRC. So we can
18	just only advise but it doesn't seem to be moving
19	forward.
20	So that would be my comment.
21	CHAIRMAN PALESTRO: Thank you. I'm
22	inclined to agree with you. Certainly at the moment,
23	it is hard to identify something that is urgent and
24	there is no way to know about urgency looking into the
25	future. On the other hand, I think it is nice to know
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1	or to have the sense that if we do feel there is an
2	urgent need for a meeting, that we have the support of
3	staff and management, in the event that we so desire.
4	Any other comments or questions?
5	MS. HOLIDAY: Dr. Palestro, if I could
6	just quickly respond, and I'm sorry if I am going to,
7	perhaps, steal your thunder, Chris.
8	But with respect to the timeliness of
9	responding to the actionable items, if you'll notice,
10	a lot of the items we close, we closed several charts
11	in the fall meeting because they were all tied to the
12	rulemaking effort. And as a federal agency, we have
13	to follow our regulatory process in terms of
14	rulemaking efforts. That means that we have to engage
15	members of the public. We have to satisfy all the
16	steps, and there is a flow chart, all of the steps
17	that you have to do for a rulemaking.
18	So for rulemakings, you know we always
19	joke about how it took ten years to push this rule out
20	and ideally, you know we would like things to hit the
21	street within six months. But the reality of it is in
22	order to give a topic, especially one that can be as
23	sensitive and as controversial as medical, that
24	rulemaking got extended and there were several
25	questions. At one point, the ACMUI members
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1	participated in specifically a Commission meeting
2	regarding a permanent implant brachytherapy, if I
3	recall. Correct? I see a couple of nods in the
4	audience.
5	So because of things like that, that is
6	why some of the items take us longer to close and it
7	is not because we don't want to take action or that we
8	aren't taking action. Our action may be to we are
9	addressing it but we still have to follow that
10	regulatory process.
11	Whereas, other things, actionable items,
12	for example, some subcommittee reports related to
13	licensing guidance. As you guys know, 35.1000
14	licensing is a much more nimble, quicker effort than a
15	rulemaking. As of lately, we have been able to push
16	out 35.1000 licensing guidance within about a year
17	time frame, which is significantly faster than a
18	rulemaking.
19	With regard to rulemaking, there is also
20	another process called a direct final rule, which
21	still has to go through the regulatory process but it
22	is not as it doesn't have as many steps as the Part
23	35 rulemaking that we just went through.
24	So if you guys recall, a couple of years
25	ago when Steve Mattmuller was on the committee, he
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1 talked about the decommissioning funding plan and how 2 the subcommittee and the committee, ultimately, endorsed the report that said we recommend a direct 3 4 final rule. And direct final rules are for things where we think that there will be less, or very 5 minimal, or no controversy. But if we get into that 6 7 process and there ends up being a lot of controversy, then it kicks over to the regular, normal, full blown-8 out rulemaking regulatory process. 9 So it is not to say that NRC staff is not 10 being responsive. It is not saying that we are not 11 12 taking action. It really depends on what the action 13 is. For example, the information notice that 14 15 Dr. Tapp referenced yesterday. The staff did take an They were evaluating it and, based on their 16 action. evaluation, it spurred into something else. 17 So I guess my bottom line is to say we are 18 19 doing something. We are taking action. It depends on what that particular action is. 20 21 CHAIRMAN PALESTRO: Thank you, Ms. 22 Holiday. 23 Mr. Einberg. MR. EINBERG: Yes, just to add on to what 24 25 Sophie had to say, I think the frustration from the

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1 ACMUI members may be that they don't understand why it is taking so long. So when we go through the action 2 items that we explain that this is where we are in the 3 4 process on this particular item so that they have an understanding that it is in rulemaking, rulemaking 5 takes X number of years and this is where we are in 6 the process, so that they don't have that frustration 7 and that they see that these items are being acted 8 upon. 9 Regarding the frequency of meetings, 10 Ι would also add that another option would be to have 11 12 three-day meetings, rather than two-day meetings if there are additional topics that need to be discussed. 13 CHAIRMAN PALESTRO: Thank you. Mr. Ouhib. 14 15 MEMBER OUHIB: Yes, I guess just to answer 16 the concern about you know perhaps things are not 17 being done as expected, which I am not sure I agree with that, is to sort of have some projected target 18 19 dates, more or less, but they are not set in stone, knowing that sometimes, for whatever reason, there are 20 21 things that will take longer. But at least having 22 some target date, people will sort of have an idea of 23 what to expect. MR. EINBERG: Yes, excellent idea. 24 CHAIRMAN PALESTRO: Any other comments or 25

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1	questions from the committee?
2	Attendees in the room?
3	Bridge line?
4	All right, I am just going to add one
5	final comment because we are really out of time on
6	this session.
7	And I think it would be helpful for the
8	fall meeting to include a session and explain how the
9	items that the ACMUI itself acts on or recommendations
10	we make, how they go through the pathway to final
11	resolution, like rulemaking and so forth, and give us
12	a sense of the time it takes for each of these things.
13	Because I have been on the committee for eight years
14	and I know that it takes a long time to get many items
15	accomplished but if you were to ask me specifically
16	what path, I don't have that answer, that knowledge
17	and I think it would be helpful to us. It would give
18	us a much better understanding.
19	Any other comments or questions?
20	All right, that concludes this session.
21	Thank you.
22	And now we are ready for the next, which
23	is a special presentation to Ms. Laura Weil, our
24	patients' rights advocate. And Mr. Moore will make
25	this presentation.
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1	MR. MOORE: Good morning, ACMUI. Good
2	morning, Chairman. Good morning, Dr. Weil.
3	I am Scott Moore. I am the Deputy
4	Director for the Office of Nuclear Material Safety and
5	Safeguards and today I am here to recognize Dr. Weil
6	with the ACMUI, her contributions to the committee,
7	and to the NRC.
8	This is Dr. Weil's last in-person meeting
9	as the ACMUI Patients' Rights Advocate. Dr. Weil was
10	appointed as the ACMUI Patients Rights' Advocate in
11	2011 and will be completing her second and final term
12	on August 28th, 2019. She serves in a unique and
13	vital role on the ACMUI because the patients' rights
14	advocate serves as a liaison between patients and the
15	healthcare providers on the committee.
16	Patient care is of the utmost concern to
17	the NRC and we are interested in that because
18	byproduct material, obviously, is used to treat and
19	diagnose diseases and cancers.
20	She has briefed the Commission during
21	public Commission meetings on a number of occasions,
22	since she has been with the committee, including in
23	2012 actually, every year that she has been on the
24	committee from 2012 until today. In 2012 she talked
25	about medical events, 2013 she talked about patient
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1 release, 2014 she talked about radiation safety 2 instruction, 2015 was patients' rights, 2016 was more patients' 3 about rights, 2017 was training and 4 experience, 2018 was a number of different topics, it was three separate topics on T&E recommendations for 5 6 revisions to patient release and medical event 7 And then she is again reporting to the reporting. Commission today on nursing mothers' guidelines, T&E, 8 and medical event reporting. 9 So she has the honor of having briefed the 10 Commission more than anybody else on the committee, at 11 this point, which may be a dubious honor. 12 So it 13 depends on how you look at it, I guess. If you are a problem licensee, you don't want to be in that place. 14 15 Anyway, we appreciate your doing that, Dr. 16 Weil, and the Commission appreciates it, too. 17 You have worked with NRC staff to develop a Federal Register notice to request information from 18 19 the public on patient information and quidance existing on websites and available brochures. 20 And 21 most recently, you provided the staff in our office 22 with comments on the patient release brochure. Since being on the committee, she has 23 attended a number of thyroid cancer 24 survivors' 25 meetings in her role as the patients' rights advocate.

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1 And in addition to the things that I just mentioned, we have also benefitted from her experience on a 2 number of high priority issues, including hormesis 3 linear non-threshold, abnormal occurrence reporting, 4 5 proposed amendments to the ACMUI bylaws, proposed revision to our NRC policy statement on abnormal 6 occurrence reporting, the issue of the 700 hours 7 training and experience, the impact of medical event 8 reporting on medical licensee patient safety, patient 9 intervention, and the physical presence requirements 10 for the Leksell Gamma Knife. 11 She also served as the chair of the 2019 12 13 ACMUI Bylaws Subcommittee. So at this time, we would like to present 14 you with a few tokens of our appreciation. Sophie, I 15 16 would like to ask you to come up, and Dr. Weil. 17 MEMBER WEIL: I appreciate the promotion 18 but I am not a doctor. 19 MR. MOORE: Oh, I'm sorry, Ms. Weil, yes, actually. 20 21 So Sophie, if you could hand this to her. 22 Yes, and Kellee, too. Yes. We have a flag that was flown over the 23 Capitol and a certificate from Senator Van Hollen; a 24 25 certificate of appreciation from Chairman Svinicki;

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1	and finally, a gold lapel pin from the NRC.
2	And so I would just like to tell you from
3	myself, from the staff, and from the NRC as a whole,
4	thank you so much for your service. The Patients'
5	Rights Advocate is a very important role for us, the
6	staff. The committee, as you all know, is filled with
7	medical experts, with government officials, with
8	states' representatives but the patients' rights
9	advocate plays an extremely important role.
10	To us, you know you are representing
11	patients that are out there and we listen very heavily
12	to the comments that you provide. You have been on
13	the committee for a long time and we really, really
14	appreciate your input. So thank you from the staff
15	and from the agency.
16	Would you like to make any comments?
17	MEMBER WEIL: Yes, but I would like to sit
18	down.
19	MR. MOORE: Okay, great. Thanks.
20	MEMBER WEIL: Well thank you very much for
21	reminding me of all the things I've been engaged in
22	because I had forgotten most of that.
23	When I first began my first term on the
24	ACMUI, I was prepared to face a fair amount of
25	suspicion, if not outright hostility in my role as a
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1	professional patients' advocate.
2	Someone who calls herself a patients'
3	advocate needs always to be ready for the dangers of
4	usurping that title from others who justifiably see
5	themselves as advocates as well. Almost everyone who
6	works in the healthcare arena has opportunities to
7	advocate for what patients need and often, the front
8	line workers are the unsung heroes in this endeavor.
9	But I was surprised that there was very
10	little, if any, of that reaction here at NRC. And as
11	you will hear me state to the Commissioners, I believe
12	that just about every one of the ACMUI members I have
13	had the privilege to work with over the last nearly
14	eight years has considered patient advocacy an
15	essential core of his or her professional ethic.
16	In my academic career, I used to tell my
17	students that there is patient advocacy with a small p
18	and patient advocacy with a capital P. And that
19	uppercase P represents a more zoomed-out perspective,
20	advocating for groups and populations, rather than the
21	needs of a single small p patient.
22	The uppercase P is certainly the focus of

advocacy here at the ACMUI and it needs to be 23 differentiated from what most healthcare workers can 24 accomplish in the course of their often overwhelming 25

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1	primary responsibilities. The uppercase P is what has
2	driven my belief that it is perfectly appropriate for
3	a regulatory agency like NRC to require and not just
4	recommend guidance timely education for patients who
5	are administered radiopharmaceuticals such that they
6	are able to understand, and plan, and effectively
7	protect those around them from unnecessary exposure to
8	radiation. That's a public health issue and it isn't
9	stepping on the toes of the practice of medicine.
10	The uppercase P drives the need to make
11	sure that healthcare providers are competent to use
12	radiopharmaceuticals and have received appropriate
13	training and experience. Indeed, the uppercase P
14	drives much of what the ACMUI tries to accomplish in
15	terms of promoting safety, accessibility, and
16	fairness.
17	That uppercase P also prompted me to
18	repeatedly remind the committee that all of the
19	distinguished professionals in this room work at
20	Centers of Excellence and represent the best of the
21	best in health care. And everyone needs to remember
22	that not all patients experience health care the way
23	it is provided in your facilities. Not all medical
24	personnel have the support that is likely provided in
25	the facilities where you work.
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1	Regulation needs to be appropriate for the
2	best facilities but more essentially, it needs to
3	ensure protections for patients and workers in those
4	less-than-best environments, where most health care is
5	delivered in the United States.
6	It has really been a privilege to serve
7	with you and I wish you the very best going forward.
8	MR. MOORE: Congratulations, Ms. Weil. I
9	would like to thank the committee and the chairman for
10	the opportunity to recognize Ms. Weil as well as her
11	briefings to the Commission. And if anybody beats her
12	record of eight presentations to the Commission we
13	are keeping track. So, congratulations.
14	MEMBER WEIL: Thanks.
15	MR. MOORE: Mr. Chairman.
16	CHAIRMAN PALESTRO: Laura, you and I have
17	been on the committee for just about the same length
18	of time and I have always come to think of you as the
19	conscience of the committee, reminding us that, as we
20	are going through our various discussions about
21	education and experience, and the various rules and
22	regulations, and so forth, reminding us that
23	ultimately, at the end of the day, it is centered on
24	the best in care and safety for the patient. The
25	patient is of the utmost importance.
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1	Now on a personal note, Northwell Health
2	owes you a vote of thanks. A few years ago you had
3	presented the results of a survey that you had done on
4	patients with thyroid cancer. And one of the things
5	that you you discussed many things but one of the
6	things that you discussed that stuck in my mind
7	because I am responsible for several institutions, was
8	the variation in instructions that patients got from
9	one institution or one physician to another and how
10	disconcerting that was, not necessarily that the
11	instructions, the variations were wrong or incorrect
12	but there were variations and the patient didn't know
13	what to do.
14	And so I decided that it was time probably
15	to go back and relook at what I had assumed to be
16	consistent instructions from site to site and found
17	that they weren't so consistent and that they did
18	vary. And as the patients moved from one institution
19	to another, they would get one set of instructions or
20	another and that clearly caused them angst.
21	So as a result of your comments and my
22	review of that, it took us a while, but I think that
23	you would be pleased to know, and I know that our
24	patients are, that we finally have it down, for at
25	least our thyroid cancer patients, to a uniform set of
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1	instructions and guidelines. And for that, we are
2	deeply indebted. Thank you.
3	Anyone else who would like to say
4	anything?
5	Dr. Ennis.
6	MEMBER ENNIS: I just wanted to echo what
7	other people have said, that in the almost four years
8	I have been on the committee, I have always found your
9	comments to be extremely thoughtful, sharpening the
10	debate, the discussion, extremely well expressed, and
11	always a significant contribution to any conversation.
12	So personally, I have enjoyed getting to
13	know you and forming a friendship as well but your
14	professional contributions go beyond the specific
15	presentations that you have made but the role that you
16	have had in regular discussions and all your
17	subcommittees has just been really extremely valuable.
18	CHAIRMAN PALESTRO: Any other comments?
19	Dr. Metter.
20	VICE CHAIRMAN METTER: I haven't been on
21	the committee as long as everybody else. This is, I
22	believe, my third year. And I have always looked
23	forward to your wise comments, your excellent
24	delivery. And you were not afraid.
25	And as far as the patients' rights
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1	advocate, if a patient were here, I mean they would be
2	very proud of what you stand for for them.
3	And you know there would be discussion and
4	then all of a sudden, Laura's hand would go up and
5	there would be like uh-oh. And the thing is that you
6	would bring a perspective that we are so tunneled in
7	that it would be oh, yes, I forgot about that. And
8	something like what Dr. Palestro said, you know
9	something we take for granted that you bring up and
10	really you are a true patient advocate.
11	And thank you for all the work that you do
12	and really you've opened up the ACMUI to even getting
13	better in what they do. Thank you.
14	CHAIRMAN PALESTRO: Mr. Ouhib.
15	MEMBER OUHIB: Yes, I just want to thank
16	you, Laura, for everything you've brought to the
17	table.
18	It's always good to have a compassionate
19	person that reminds everybody that numbers are good,
20	rules are good, but I think more than everything else,
21	don't forget to be compassionate in everything you do
22	because that is what it will come down to. Thank you.
23	CHAIRMAN PALESTRO: Anyone else?
24	Mr. Einberg.
25	MR. EINBERG: Yes, hi, Laura.
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1	So I hired, Laura. I was one of the
2	people who interviewed Laura. And when we went out
3	and were looking for a patients' rights advocate in
4	the position, this is a very difficult position to
5	fill, and we really lucked out with Laura. She has
6	made tremendous contributions to the ACMUI. She has
7	been conscious of the staff here and she has done
8	wonderful.
9	And so we are in the process of looking
10	for a new ACMUI patients' rights advocate and that is
11	going to be a very tough position to fill and very big
12	shoes to fill.
13	So thanks once again. And any advice you
14	have for us regarding what we should look for in a
15	future patients' rights advocate would be appreciated
16	and we can talk offline about that.
17	Thank you.
18	CHAIRMAN PALESTRO: Anyone else?
19	Dr. Howe.
20	DR. HOWE: I've probably seen more ACMUI
21	meetings than anyone else in this room and I have been
22	through probably including Scott and I've been
23	through a number of different patients' rights
24	advocates that we have had on the ACMUI. And I have
25	to tell you Laura has set the bar extremely high. She
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1	has been one of the best patient advocates we have
2	had.
3	And I hope in the future we are able to
4	make a decision that brings a new patient advocate in
5	that will meet her high standards because it has been
6	very important to the ACMUI to have that different
7	perspective and she has contributed a tremendous
8	amount to the NRC and the ACMUI.
9	Thank you, Laura.
10	CHAIRMAN PALESTRO: Dr. Dilsizian.
11	MEMBER DILSIZIAN: Well, Laura, when I
12	joined the ACMUI, I had no expectation of what the
13	patient advocate was going to be promoting, except my
14	experience with the IRBs. I had a lot of patient
15	advocates in the IRB meetings. You know usually their
16	comments are directed to the patient consent form,
17	understanding of the wordings, et cetera.
18	But I have learned so much from you. I
19	have served in so many committees with you. Not only
20	do you provide insight, you also are you edit a lot
21	of our reports very accurately and correctly. And I
22	have to say that you have also taught me that our
23	perspective here is really, as you said, from
24	university hospitals, where we tend to forget. And
25	several times you pointed out to me, I said this is
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1	how we do it at Maryland and you said but that's not
2	normal. And then that was kind of unusual for me to
3	hear that and I think I learned a lot from you. And
4	yes, I have a different perspective.
5	And I also respect that you are willing to
6	change your mind. A lot of times, you start with a
7	certain opinion. After discussions, you kind of
8	change. And that is big.
9	Thank you very much.
10	CHAIRMAN PALESTRO: Anyone else?
11	MS. HOLIDAY: Does anybody before I go?
12	Okay. So unlike Donna-Beth, I have not
13	been around for as many ACMUI meetings but I have been
14	around for all of Ms. Weil's ACMUI meetings. And
15	after hearing what everybody has said, you know it is
16	absolutely true.
17	And one of the remarkable things about Ms.
18	Weil is that she is so humble. You were humble every
19	time you were placed on a subcommittee. And she is
20	the first person to say, you know I am not the subject
21	matter expert and I don't have any technical expertise
22	but then you come in and you add so much value to the
23	discussions, to the report. You have wordsmithed the
24	heck out of everything, out of our patient release
25	brochure. The staff has reached out to Ms. Weil on
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1	numerous occasions as it relates to patient release.
2	And we are very, very fortunate to have
3	had you here on the committee. We have been around
4	for the birth of children, for the birth of
5	grandchildren. We are the fellow vertically-
6	challenged people and I am happy to be able to call
7	you a friend.
8	So congratulations and thank you.
9	CHAIRMAN PALESTRO: Anyone else?
10	All right, Laura, I think what we've heard
11	sums up everything about you and, again, on behalf of
12	myself and the committee, everyone here, our sincere
13	thanks for your eight years of service and we hope we
14	don't lose touch.
15	Thank you very much.
16	All right, that concludes this session.
17	We are on a break now until ten o'clock. The
18	Commission meeting is in White Flint One. All right,
19	very good. We will see you there. Thank you.
20	(Whereupon, the above-entitled matter went
21	off the record at 9:25 a.m. and resumed at 1:15 p.m.)
22	CHAIRMAN PALESTRO: All right, welcome
23	back. We will call this afternoon's final session to
24	order.
25	Before we proceed into the formal part of
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1	the program, I just want to thank Doctors Metter,
2	Ennis, and Ms. Weil for their contributions and
3	presentations at this morning's session with the
4	Commission. It certainly obviously, I am
5	prejudiced because I was part of it, but I think it
6	was the best of all the sessions that I have been
7	involved with the commissioners. I thought it was an
8	excellent dialogue and I received compliments from
9	many people. And I really appreciate that and it
10	really goes to all of you folks.
11	And in fact some woman, who I have no idea
12	who she was, stopped me on the street and said good
13	meeting, Palestro. So, whoever it was, I think we did
14	a good job.
15	(Laughter.)
16	CHAIRMAN PALESTRO: That may be a custom
17	here in Rockville and Bethesda.
18	So thank you all very much. I appreciate
19	that job well done.
20	All right. So we are going to move on to
21	the next topic, the ACMUI Bylaws Subcommittee Report
22	and Ms. Weil will present this.
23	MR. WILLIAMS: Dr. Palestro, if I could, I
24	want to correct the record.
25	Thank you. Before we get into the
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1	presentation, I wanted to before the break and Mike
2	Fuller and I had this conversation during the
3	Commission meeting, I wanted to just correct one thing
4	on the record.
5	We were talking about the advantages or
6	disadvantages of ACMUI reporting either to the
7	Commission or staying at the same place with reporting
8	to the Division Director. And one of the comments
9	that was made is that the and I am paraphrasing but
10	that the staff had nothing to offer.
11	And what I wanted to correct was the staff
12	has a vast amount of knowledge and expertise in terms
13	of health physics and things of that nature. What is
14	being supplemented is the vast expertise that the
15	ACMUI Committee brings in a variety of areas that we -
16	- you know so we have identified the gap. And
17	together, I think we work very well and complement
18	each other, and we are able to provide and address a
19	number of activities.
20	So, thank you.
21	CHAIRMAN PALESTRO: Thank you, Mr.
22	Williams.
23	All right, now we are going to proceed to
24	the Bylaws Subcommittee report with Ms. Weil.
25	MEMBER WEIL: Thank you. Can I have the
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1	next slide? Do I have control of the slides? Thank
2	you.
3	So I would like to thank my fellow
4	subcommittee members, Robert Schleipman, Michael
5	Sheets, Megan Shober, and our staff resource was
6	Sophie Holiday.
7	The subcommittee charge was to review the
8	ACMUI Bylaws and recommend updates, with particular
9	focus on the question of whether the ACMUI chair may
10	serve as a member or a chair of any subcommittee.
11	So we considered two issues. Should the
12	ACMUI chair be allowed to participate in the
13	subcommittees and, if so, in what capacity? And what
14	language, if any, should be added to the bylaws to
15	clarify this question?
16	And we also considered whether there were
17	any other clarifications or additions to the ACMUI
18	bylaws that should be considered.
19	Regarding the ACMUI chair participation on
20	subcommittees, it has been the practice of the NRC to
21	prohibit the participation of the ACMUI chair in
22	subcommittee deliberations and recommendations. This
23	was recently brought to the attention of the incoming
24	ACMUI chairman, Dr. Palestro, who was asked to
25	relinquish his position as chair of an ongoing
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1	subcommittee in anticipation of his role as ACMUI
2	chairman.
3	Dr. Palestro felt that this issue should
4	be investigated by a subcommittee and an explicit
5	recommendation be made to the ACMUI with potential
6	clarification in the ACMUI bylaws. The current ACMUI
7	chair and vice-chair would not vote on the
8	recommendation put forth by this subcommittee.
9	ACMUI bylaws do not address this point,
10	nor does the ACMUI charter. The documents of our
11	sister NRC Federal Advisory Committee, the Advisory
12	Committee on Reactor Safeguards, is also generally
13	silent on the issue, although the ACRS chair is the
14	designated chair of a standing subcommittee. We don't
15	have standing subcommittees.
16	There is no discussion of this issue on
17	the FACA website, nor did consult with FACA staff
18	suggest any required position on the issue.
19	Several other FACA committee bylaws and
20	charters were reviewed by the subcommittee and none
21	had explicit language regarding the potential for
22	chair membership and participation in subcommittee
23	work.
24	The understood rationale for the existing
25	informal prohibition is that the role of the chair is
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1	onerous and time-consuming and it would be an
2	imposition to expect the chair to undertake additional
3	is this slide 4? Do we have slide 4? It doesn't
4	matter. We can go forward to undertake any
5	additional responsibilities.
6	And the second rationale is that the chair
7	might, exert undue influence on subcommittee
8	deliberations.
9	Can you go forward to slide 4? Okay.
10	Section 1.3.6 of the ACMUI Bylaws
11	explicitly states the chair may take part in the
12	discussion of any subject before the ACMUI and may
13	vote. The chair should not use the power of the chair
14	to bias the discussion. And any dispute over the
15	chair's level of advocacy shall be resolved by a vote
16	on the chair's continued participation in the
17	discussion of the subject.
18	Each member of the ACMUI has a specific
19	area of expertise and in some cases, there is no
20	duplication of expertise among all members. The
21	subcommittee felt that any subcommittee should be able
22	to avail itself of the relevant expertise of any
23	member of the ACMUI. The potential for benefit of any
24	given subcommittee outweighs the potential for undue
25	influence by the position of the chair.
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1	So here is an example. Recent
2	subcommittee relating to gamma stereotactic
3	radiosurgery licensing guidance, only one member of
4	the ACMUI had specific and significant GSR experience.
5	Had that member been the ACMUI chair and prohibited
6	from subcommittee participation, the subcommittee
7	would have been deprived of essential information and
8	input in its deliberations.
9	Concern was expressed that the ACMUI
10	chair's participation on a subcommittee should not
11	overburden or compromise the ability of the chair to
12	perform the duties of ACMUI chair. So it is proposed
13	that the ACMUI chair not be asked to serve as a
14	subcommittee chair.
15	The subcommittee also discussed whether
16	explicit bylaws language is required to address the
17	question or whether a formal position expressed and
18	captured in the ACMUI meeting would be adequate. The
19	membership of the ACMUI turns over completely every
20	eight years or sooner and NRC staff rotate in and out
21	of the medical team with unpredictable frequency. It
22	is challenging to research areas of tradition and
23	practice such as this. The minutes and transcripts of
24	ACMUI meetings, while available, aren't indexed by
25	subject.
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It was felt that there are potential limits to ACMUI institutional memory such that inclusion of specific language in the bylaws would be beneficial and the most efficient way to address this issue.

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

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

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

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1	from discussion of any agenda item in which they have
2	a 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
14	affect the personal financial interest of a spouse,
15	minor child, the organization in which they serve as
16	an officer, director, trustee, general partner, or
17	employee, an organization in which they are
18	negotiating or have an arrangement for prospective
19	employment.
20	However, the subcommittee welcomes staff
21	input on other language that would still provide
22	adequate clarification if this is not thought to be
23	useful.
24	So, in summary next slide we
25	recommend that the ACMUI chair should be permitted to
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1	serve as a subcommittee member, not chair, when his or
2	her specific expertise is necessary and a specific
3	statement to that effect should be included in the
4	ACMUI bylaws.
5	And the subcommittee recommends that more
6	explicit language be included in the bylaws defining
7	conflict of interest with respect to participation of
8	individual ACMUI members in discussion of matters that
9	come before the committee.
10	Thank you.
11	CHAIRMAN PALESTRO: Any comments from
12	other members of the subcommittee?
13	MEMBER SCHLEIPMAN: I have one comment.
14	The second slide erroneously refers to me as M.D. I
15	guess I got promoted like you earlier today. So just
16	for the record that that could be removed.
17	CHAIRMAN PALESTRO: Any other comments or
18	questions from the subcommittee? From the committee?
19	Mr. Ouhib.
20	MEMBER OUHIB: Yes, can we go back to
21	slide number 8, please? I'm not sure if I am in favor
22	of that statement members cannot participate in the
23	review of any particular matter.
24	I think as long as the conflict of
25	interest is disclosed, okay, to the chair, basically,
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1	or to the subcommittee, or whatever, I don't see why
2	that member should not participate without voting, per
3	se. Because that person might very well have valuable
4	information to the committee but then they will up-
5	front disclose as the conflict comes because six
6	months from now there was no conflict but all of a
7	sudden now, there is a conflict.
8	They can simply disclose it at the very
9	beginning but then they should be able to participate
10	but perhaps they should not be voting.
11	CHAIRMAN PALESTRO: This issue actually
12	came up, I believe, at the last meeting and there was
13	in fact a conflict of interest or a potential conflict
14	of interest and it was decided that individual could
15	not participate on the subcommittee.
16	And in fact a decision, and correct me if
17	I am wrong, Ms. Holiday, but that decision really went
18	beyond the ACMUI's choice. That went I guess through
19	legal. Is that right?
20	MS. HOLIDAY: That is correct. And just
21	for clarification, in the existing ACMUI bylaws
22	Section 4.1, the language specifically states if a
23	member believes that he or she may have a conflict of
24	interest with regard to an agenda item to be addressed
25	by the ACMUI, this member should divulge it to the
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1	chair and the DFO as soon as possible and before the
2	ACMUI discusses it as an agenda item. ACMUI members
3	must recuse themselves from discussion of any agenda
4	item in which they have a conflict of interest.
5	This is also covered in your annual ethics
6	training. As it so happens, we have some
7	representatives from the Office of General Counsel
8	here.
9	MS. HOUSEMAN: Hi, Esther Houseman
10	MS. HOLIDAY: Esther, you have to push the
11	button. There is a gray button.
12	MS. HOUSEMAN: Esther Houseman, Office of
13	the General Counsel.
14	I just want to quickly point out that it
15	looks to me like this provision from the ACRS bylaws
16	is a restatement of the Office of Government Ethics
17	rule on financial conflict of interest. So these are
18	actually Office of Government Ethics requirements and
19	nothing in the ACMUI's or the ACRS's charter, or
20	bylaws, or NRC regulations can change that.
21	And so if you are to revise the conflict
22	of interest provisions in the ACMUI bylaws, in
23	addition to the staff, the NMSS staff, the Office of
24	the General Counsel can review those and provide input
25	to ensure that they align with the Office of
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1	Government Ethics rules.
2	MS. HOLIDAY: Thank you.
3	And just to follow-up to what Ms. Houseman
4	just said, Section 5.4 of the bylaws says the ACMUI
5	shall consult with the Office of General Counsel
6	regarding conflicts that arise from the interpretation
7	of the bylaws. After consultation, the ACMUI shall
8	resolve interpretation issues by a majority vote of
9	the current membership of the ACMUI.
10	So basically, the process I don't see
11	many members here from back when we passed the bylaws
12	in 2014, except for maybe the latter part of this
13	table. The ACMUI had made recommendations to change
14	the bylaws in 2014. So after we revised those bylaws
15	in a public meeting, so that everybody could see the
16	language that was proposed and agreed to, it had to go
17	through our Office of General Counsel for them to give
18	us what they call a no legal objection, meaning that
19	there is nothing legally objectionable to it. And
20	that from there, it could be finalized.
21	So as Ms. Houseman stated, this language
22	is directly from OGE, the Office of Government Ethics.
23	It is a more detailed explanation than what is
24	currently in our bylaws. So all Ms. Weil's
25	subcommittee was doing was wanting to update the
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1	language that I had initially read to correspond to
2	the language that is verbatim from OGE and,
3	coincidentally, captured in the ACRS bylaws.
4	CHAIRMAN PALESTRO: Thank you, Ms.
5	Holiday.
6	Dr. Dilsizian.
7	MEMBER DILSIZIAN: Yes, I completely
8	agree. I think that even if if you have a conflict
9	and you are in the discussion, period, you can
10	convince other people's minds. So that is the reason
11	I think it should be completely and you know any
12	organization, any meeting, any Board of Directors, if
13	you remember, you always recuse yourself. You never
14	really try to convince the others.
15	Even though your expertise may be unique,
16	I think that this is the proper way, in my opinion.
17	Now regarding your presentation, Laura, I
18	think could you go back to maybe six, slide 6?
19	Okay, so I agree with you that the concept
20	that if the chair has unique experience, obviously, he
21	should serve as a member. You say in these
22	circumstances, the ACMUI chair will not chair the
23	subcommittee.
24	In my opinion, it is not only in these
25	instances. In any other instances, the chair should
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1	not chair a subcommittee. You know what I am saying?
2	It just seems like others
3	MS. HOLIDAY: So is there a motion on the
4	table to amend the recommendation?
5	CHAIRMAN PALESTRO: I am not done.
6	MS. HOLIDAY: Sure.
7	CHAIRMAN PALESTRO: Ms. Weil, you are
8	reporting the case that the ACMUI chair, under certain
9	circumstances, can serve on a subcommittee. The
10	question is, who makes the determination, the
11	subcommittee chair or the ACMUI chair?
12	MEMBER WEIL: So the ACMUI chair would be
13	establishing the subcommittee, correct? You establish
14	our subcommittees.
15	CHAIRMAN PALESTRO: That's correct.
16	MEMBER WEIL: And so I would think that it
17	would be the chair of the subcommittee. You choose a
18	subcommittee. The chairman of the ACMUI
19	CHAIRMAN PALESTRO: That's correct, yes.
20	MEMBER WEIL: chooses the subcommittee,
21	designates a chair of that subcommittee, and that
22	chair then would be the person to request the
23	participation of the appropriate specialist, who
24	happens to be the ACMUI chair.
25	CHAIRMAN PALESTRO: Thank you.
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1	Mr. Sheetz.
2	MEMBER SHEETZ: I just want to comment on
3	that. I would think that the chair would be able to
4	appoint him or herself to the subcommittee and, if the
5	chair did not appoint him or herself to subcommittee,
6	the subcommittee chair could ask the chair to serve on
7	that committee, should they feel that that expertise
8	was necessary.
9	That covers all ends.
10	CHAIRMAN PALESTRO: Dr. Ennis.
11	MEMBER ENNIS: So the point of these kinds
12	of rules are to avoid abuse of power. It feels a
13	little like okay, that's not going on. Now we're all
14	getting along and all of that. But the point of this
15	is well what happens if there is an issue, which has
16	happened in the past, from what we understand. Most
17	of us weren't here then.
18	So I feel a little uncomfortable about the
19	notion that the chair appoints his friend, who then
20	will turn around and appoint his friend back on the
21	committee. That feels too cozy and allows for a
22	little bit of abuse of power over what kind of
23	relationship those two might have in all kinds of
24	ways.
25	So I would prefer that this exception in
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1	allowing the chair to be on a subcommittee be
2	something that either the entire ACMUI has to vote on
3	or the subcommittee in its entirety has to vote on.
4	MS. HOLIDAY: Dr. Ennis, thank you for
5	raising that point. So I will also read for you
6	Section 1.3.6 of the bylaws. And it states the chair
7	may take part in the discussion of any subject before
8	the ACMUI and may vote. The chair should not use the
9	power of the chair to bias the discussion. Any
10	dispute over the chair's level of advocacy shall be
11	resolved by a vote on the chair's continued
12	participation in the discussion of the subject.
13	So one could say that you could either
14	reference Section 1.3.6, if that is the recommendation
15	of the committee, you can model it after the language
16	in Section 1.3.6. But I do want to make you aware of
17	the language that is currently in the bylaws.
18	MEMBER WEIL: What we are suggesting is
19	that this statement follow and be included in 1.3.6
20	but be included in that paragraph.
21	CHAIRMAN PALESTRO: Any other comments or
22	discussion?
23	Comments/questions from attendees in the
24	room? Bridge line?
25	Dr. Howe.
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1	DR. HOWE: I just had a question. When
2	you are proposing to change the conflict of interest,
3	it seems to be only addressing financial reasons.
4	In some cases in the past, we have had
5	and I don't think this would be necessarily financial,
6	but we have had cases where maybe a member of the
7	ACMUI has a licensing action in front of the NRC and
8	that might be a conflict of interest for that person
9	to be actively representing a certain position on that
10	type of licensing action.
11	So I think the conflict of interest is a
12	little broader than just financial. I think you
13	should consider.
14	CHAIRMAN PALESTRO: Ms. Weil, any comments
15	on that?
16	MEMBER WEIL: Yes, I looked at other
17	conflict of interest statements in other advisory
18	committee bylaws and they can run to several pages.
19	And I guess I would rely on our counsel to suggest
20	whether or not our bylaws need additional language, or
21	whether the statement well, not counsel on us to
22	decide whether we need additional language or whether
23	or not we just can rely on that statement where we
24	refer back.
25	I felt there needed to be further
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1	clarification because conflicts do come up in this
2	committee. They do come up and we had one recently.
3	And I think we could all use a bit of guidance.
4	I guess I would love to open this to
5	subcommittee members about whether you think we need
6	the broad description of conflict.
7	MEMBER SCHLEIPMAN: So this is Robert.
8	I agree with Dr. Howe that there can be
9	other conflicts. And the existing language in 4.1
10	permits all of the you know more than financial
11	conflicts to be addressed or reviewed.
12	I think what you are asking, perhaps, or
13	suggesting is that all of the committee members have a
14	clear understanding of what types of situations may
15	constitute a conflict. Most people know but perhaps
16	we are not regularly familiar with the Code of Ethics,
17	although we have reviewed it and so forth.
18	And so if there is just a reference to
19	what are the descriptions for a conflict of interest,
20	that may be fine, rather than substituting the broader
21	language, which permits consideration of all types of
22	conflicts.
23	CHAIRMAN PALESTRO: Mr. Green.
24	MEMBER GREEN: In light of the comment to
25	be not quite so specific, to focus purely on financial
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1	interest, if we go to slide 8 in the proposed
2	language, as proposed by the subcommittee, if we
3	struck the word financial out of the fourth row, to
4	predictably affect their personal interest or the
5	financial or again, I guess we would strike
6	financial twice out of that first paragraph. If we
7	struck that word out twice, then it is not solely
8	focused on financial matters but also include
9	licensing activities of all of these items below.
10	MEMBER WEIL: I believe we just heard that
11	we can't alter the language, that we need to use the
12	language that already exists.
13	MS. HOUSEMAN: OGC would review whatever
14	proposal you put forth and could assist in drafting
15	language, again, that aligns with the government
16	ethics rules. And it all depends on just to what
17	extent do you want to summarize and incorporate the
18	government ethics rules into your bylaws to serve as
19	just an additional place where you can look to think
20	about is there a conflict of interest here.
21	I don't think that striking the term
22	financial would work, again, because I think that this
23	restatement captures specifically the financial
24	conflict of interest government ethics rule.
25	MEMBER WEIL: Is there a reference
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1	document that we can refer to in the bylaws that
2	rather than restating it, can we just reference it as,
3	Dr. Schleipman asked?
4	MS. HOUSEMAN: We could find the
5	regulatory references so to the particular government
6	ethics rules, if that is what you are asking.
7	MEMBER WEIL: That might be the most
8	efficient way to approach this.
9	MS. HOUSEMAN: It might be, yes.
10	MEMBER WEIL: Efficient is good.
11	CHAIRMAN PALESTRO: Mr. Ouhib.
12	MEMBER OUHIB: Yes, just I would make a
13	suggestion. Perhaps for every subcommittee at the
14	beginning of each session to sort of remind people
15	about the conflict of interest to state that. And
16	that is very common in several medical organizations
17	when there is a task group or whatnot to actually at
18	the very beginning state that if you have any conflict
19	of interest to state it now and remove yourself.
20	Because you just never know. It is sort of like
21	reminding people about that policy.
22	CHAIRMAN PALESTRO: Mr. Ouhib, just so
23	that it is clear in my mind what you said, that you
24	would like to have a conflict of interest reviewed at
25	the beginning of every meeting and every telephone
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1	conference?
2	MEMBER OUHIB: Not necessarily review it
3	but state it sort of as a reminder to people that if
4	you have a conflict of interest, that you need to
5	remove yourself from any discussion that is going to
6	take place.
7	CHAIRMAN PALESTRO: I think that that is
8	an excellent point.
9	Mr. Einberg.
10	MR. EINBERG: Maybe we could add that to
11	the opening remarks.
12	CHAIRMAN PALESTRO: Thank you.
13	Any other comments or questions?
14	All right. In terms of the subcommittee's
15	report, it has actually got two separate components
16	and I would ask Ms. Weil and the subcommittee what do
17	you think about deferring a vote on the conflict of
18	interest until such time as legal provides us with a
19	more comprehensive or more appropriate, if you will,
20	definition?
21	MEMBER WEIL: I would suggest that the
22	report should be amended to remove the in these
23	instances statement. So the chair may serve on
24	relevant subcommittees. The ACMUI chair will not
25	chair the subcommittee. So that recommendation is
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1	amended to remove those three words: in these
2	instances.
3	CHAIRMAN PALESTRO: And you add that the
4	ACMUI chair will serve on a subcommittee at the
5	subcommittee's discretion.
6	MEMBER WEIL: Yes.
7	Okay and regarding the conflict of
8	interest, I would suggest that the report be amended
9	to state the same things, the subcommittee felt that
10	the existing language in the bylaws regarding conflict
11	of interest was vague. And then there is the citation
12	of Section 4, Conduct of Members, which describes what
13	yes, there it is.
14	And then instead of amending the bylaws
15	with language, I would just suggest that we refer in
16	Section 4.1 to the government document that we will be
17	able to cite, once we have that citation, and take out
18	all the other language about financial conflict.
19	CHAIRMAN PALESTRO: Regarding a conflict
20	of interest, is that acceptable to legal? Ms. Weil's
21	proposal, does that make sense?
22	MS. HOUSEMAN: It does but to confirm, I
23	would need to go back to the division in the Office of
24	the General Counsel that specializes in advising on
25	the government ethics rules and run it by them.
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1	CHAIRMAN PALESTRO: Thank you.
2	Any more, comments, questions, discussion
3	on these two topics?
4	All right, can I have a motion to approve
5	the amended report? Dr. Dilsizian.
6	Second?
7	(No audible response.)
8	CHAIRMAN PALESTRO: Any further
9	discussion?
10	All in favor?
11	Any opposed?
12	Any abstentions?
13	Okay and Ms. Holiday, I would like to go
14	on the record as indicating that my abstention was not
15	or should not be considered a vote against or a
16	negative vote but rather, as I stated when I formed
17	the subcommittee, abstention because of the obvious
18	conflict of interest.
19	I would like to thank the subcommittee for
20	your work on this because I found this a very vexing
21	issue, as the chair, having been so intimately
22	involved in the Training and Experience Subcommittee
23	and then being told that I had to give it up and not
24	being able to find a hard and fast reason as to why
25	documented. It was difficult.
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1 So I think you have cleared, at least for me and hopefully, for future chairs what potentially 2 can become an issue and I thank you very much for 3 4 that. And I think your rationale for doing so 5 regarding expertise was exactly something that had come up in my mind when Dr. Metter and I had talked 6 7 about it. In your report, you alluded to another 8 issue, another problem that we sometimes face and that 9 is institutional memory, going back and trying to 10 retrieve documents and so forth in the past. 11 There is 12 no good way to do it and we ran into that numerous times continually, when we tried to sort through how 13 the 700 hours for training and experience was arrived 14 15 at. 16 Having said that, I think it is reasonable 17 to form a subcommittee with a charge for improving or attempting improve ACMUI's 18 at least to the 19 institutional memory. MEMBER WEIL: I believe that the website 20 21 that has been established for ACMUI subcommittee 22 charges and reports will ameliorate that situation going forward. Do you think Sophie? 23 CHAIRMAN PALESTRO: The answer is I don't 24 25 know but one of the issues that comes up is, and you

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1	noted in your report, that while there are transcripts
2	of the meeting minutes, they aren't categorized or
3	there is no cross-referencing by subject.
4	So while I think the website improves
5	things, I'm not sure that it solves all of the issues.
6	And the truth of the matter is, the subcommittee can
7	come back and say this is as good as it gets; there
8	are no additional recommendations. I think it
9	behooves us to look at it.
10	That's my only thought. And maybe this is
11	where it ends.
12	So with that in mind, I am going to ask
13	Dr. Schleipman to chair this committee. I am going to
14	ask Ms. Shober to be a part of that; Ms. Weil, for
15	whatever time you have left, I would like to have you
16	on that; Dr. Ennis; and Dr. O'Hara because you work
17	for another federal agency and you may have some
18	unique insights into institutional memory.
19	All right, staff resource? Okay, Ms.
20	Kellee Jamerson.
21	All right and then finally, before we move
22	on to the open forum, if I could just ask the
23	subcommittee chairs, when you are presenting your
24	reports, be they slides or full reports, please make
25	sure to include the name of the staff resource on that
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1	introductory slide.
2	All right, the next item on the agenda is
3	the open forum; topics of interest previously
4	identified or maybe not identified. Anybody have
5	anything that they would like to bring up?
6	Ms. Dimmick.
7	MS. DIMMICK: Thank you. Lisa Dimmick,
8	Medical Team Leader.
9	It is more or less just a follow-up to a
10	previously discussed item and it is about the Medical
11	Event Subcommittee's recommendation for an information
12	notice. It was discussed during the Commission
13	briefing and there wasn't really an opportunity for
14	staff to provide any input to that. But I did want to
15	add that that information notice is on the Medical
16	Team's work plan for FY19. So we do plan to have at
17	least the IN drafted and hopefully starting in
18	concurrence by the end of fiscal year '19. So that
19	would be the end of September.
20	So in anticipation that there should be an
21	information notice drafted in September.
22	CHAIRMAN PALESTRO: Thank you.
23	Dr. O'Hara, a little while ago, you and I
24	were talking and I suggested that you bring up your
25	observations at the open forum. And so could I ask
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1	you to expand on it?
2	MEMBER O'HARA: Yes, yesterday we were
3	discussing the National Nuclear Safety Association's
4	plans for isotope use in the United States. And I sit
5	on a couple of their committees. So I have some
6	knowledge of what is going on. There is someone at
7	NRC who sits on that committee as well, because I have
8	heard her speak before.
9	But what I heard was concern from Ms.
10	Martin and others that we will lose the use of
11	specific isotopes. And we all know that the isotope
12	that is tops on the hit list is cesium but people were
13	mentioning other isotopes. So what I suggested to Dr.
14	Palestro was that we invite the NNSA here to tell us
15	about their where they are, where they are going
16	and so that we have the option to understand where
17	they are going and begin to push back, if they are
18	planning on getting rid of iridium or something like
19	that.
20	CHAIRMAN PALESTRO: Ms. Holiday, before I
21	open the discussion to the group, are there
22	restrictions on having invited speakers?
23	MS. HOLIDAY: No, absolutely not. If you
24	guys will remember, a couple of years ago when NNSA
25	was rolling out their GTRI program am I saying that
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1	right G-T-R-I program, NNSA came and gave
2	presentations on that. So they are not they are a
3	familiar face here.
4	So if this is something that the committee
5	wishes to hear about, then we will make the contact
6	with NNSA.
7	CHAIRMAN PALESTRO: Comments, questions?
8	MR. EINBERG: Yes, if Dr. O'Hara has a
9	contact person, that would help facilitate us making
10	that arrangement.
11	CHAIRMAN PALESTRO: Any other comments or
12	questions?
13	Ms. Martin.
14	MEMBER MARTIN: I would just speak in
15	support of that. I think it would be wonderful for
16	this committee to know what the plans are as far as
17	use of medical isotopes. Are the restrictions
18	potential restrictions on the use of certain isotopes?
19	CHAIRMAN PALESTRO: Dr. Ennis.
20	MEMBER ENNIS: Yes, I would encourage us
21	to embrace this topic. I have a lot of concerns about
22	and have heard about grumblings before. I kind of
23	alluded to it in the Commission briefing. And
24	whatever we can do to kind of engage them in dialogue,
25	perhaps even suggesting they have their own ACMUI
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1	might be good.
2	So, let's start the conversation.
3	CHAIRMAN PALESTRO: Any other comments or
4	questions? Attendees in the room? Bridge line?
5	All right, Dr. O'Hara, can I ask you to
6	put this in the form of a motion?
7	MEMBER O'HARA: I move that the ACMUI
8	contact the NNSA and ask them to come to a meeting, to
9	one of our meetings and review their plans for isotope
10	utilization in the United States.
11	CHAIRMAN PALESTRO: Second?
12	Dr. Schleipman.
13	Any further discussion?
14	All in favor?
15	Any opposed?
16	All right, thank you very much for that,
17	Dr. O'Hara.
18	And I think, recognizing that there are a
19	lot of things that need to be accomplished at these
20	meetings and so forth, that going forward we need to
21	consider having outside individuals from different
22	groups appear more often. It strikes me that over the
23	course of my eight years, most of the time the outside
24	speakers have been vendors.
25	MS. HOLIDAY: Dr. Palestro and Dr. O'Hara,
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1	if I may, I know that the committee just voted
2	unanimously for this recommendation.
3	Point of clarification: I think the
4	committee means the NRC staff will reach out, not the
5	ACMUI will reach out.
6	CHAIRMAN PALESTRO: Thank you.
7	MS. HOLIDAY: Thank you.
8	CHAIRMAN PALESTRO: Any other items for
9	the open forum?
10	All right, hearing none, we will move on
11	to the administrative closing and I will turn this
12	over to Ms. Jamerson.
13	MS. JAMERSON: So I provided a meeting
14	Doodle poll to all of the members of the committee for
15	tentative dates for the 2019 fall ACMUI meeting.
16	Again, our fall meeting occurs in either
17	September or October and, as it's been mentioned, Dr.
18	Palestro's term ends September 21st. So I wanted to
19	schedule the meeting prior to the end of his term.
20	Considering this, the selection of dates
21	for the fall meeting was rather limited. And so the
22	options that received the most votes were for
23	September 9th and 10th; September 10th and 11th; and
24	September 11th and 12th.
25	So from these dates, from these options,
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1	is there a preference of the committee for the fall
2	meeting?
3	MEMBER MARTIN: I just realized I can't
4	make any of those dates. I'm going to be out of the
5	country. I'm sorry.
6	MS. JAMERSON: So I will clarify that for
7	September 9th, Mr. Green and Ms. Martin have
8	conflicts. For September 10th, again, Mr. Green and
9	Ms. Martin have conflicts. For September 11th, Ms.
10	Martin is also away. And for September 12th, Dr.
11	Dilsizian and Ms. Martin have conflicts.
12	MEMBER DILSIZIAN: I could potentially
13	make the 12th.
14	MS. JAMERSON: Okay.
15	MEMBER GREEN: I could potentially make
16	the 10th. I'd just have to do some travel
17	arrangements.
18	MS. JAMERSON: So I propose from this that
19	September 11th and 12th as the first option and, for
20	the backup dates, would be September 10th and 11th.
21	Is that okay with the committee?
22	CHAIRMAN PALESTRO: Works for me.
23	Other members? Ms. Martin.
24	MEMBER MARTIN: Point of clarification.
25	Since you gave me the subcommittee that is supposed to
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1	report back at this meeting, do you want me to try and
2	get the report meeting and have some other member of
3	the committee give it or hold the subcommittee report
4	until the spring meeting?
5	CHAIRMAN PALESTRO: There are a couple of
6	ways it could be done. One, is to prepare the report
7	and have someone designated from your subcommittee.
8	That might be the easiest.
9	MEMBER MARTIN: Okay.
10	CHAIRMAN PALESTRO: Alternatively, we
11	could hold a telephone conference meeting over the
12	summer.
13	MEMBER MARTIN: Okay.
14	CHAIRMAN PALESTRO: All right. I would
15	rather not delay it beyond the fall meeting.
16	MS. JAMERSON: Okay.
17	CHAIRMAN PALESTRO: I'm sorry, Ms.
18	Jamerson, for me could you repeat the days?
19	MS. JAMERSON: Yes, so our fall meeting
20	will be September 11th and 12th and our backup date
21	will be September 10th and 11th.
22	CHAIRMAN PALESTRO: Thank you.
23	MS. JAMERSON: So the other portion of our
24	administrative closing is where we review any of the
25	new recommendations or actions that have occurred
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1	during the course of this two-day meeting.
2	First, the ACMUI endorsed the Yttrium-90
3	Microsphere Brachytherapy Licensing Guidance, Revision
4	10 Subcommittee report and the recommendations therein
5	with the caveat that the term drug be changed to
6	device. Do you agree?
7	CHAIRMAN PALESTRO: Yes.
8	MS. JAMERSON: Okay. Secondly, Dr.
9	Palestro formed a Subcommittee to Reevaluate the 1980
10	Infiltration Decision and report to the committee at
11	the fall 2019 meeting with any recommendations. The
12	subcommittee members include Dr. Dilsizian, Mr. Green,
13	Ms. Martin as the chair, Mr. Sheetz, Ms. Shober, and
14	Ms. Weil. And the staff resource for this is Maryann
15	Ayoade.
16	Do you agree?
17	CHAIRMAN PALESTRO: Yes.
18	MS. JAMERSON: For item 5, the ACMUI
19	endorsed the Germanium-68/Gallium-68 Generator
20	Licensing Guidance, Revision 1 Subcommittee report and
21	the recommendations therein.
22	Do you agree?
23	CHAIRMAN PALESTRO: Yes.
24	Question: Can this item now be closed or
25	not? No. Can you explain why, Ms. Holiday, again?
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1	MS. HOLIDAY: Sure. So at the present
2	time, this is ACMUI providing its recommendations for
3	revisions to the Germanium/Gallium-68 Generator
4	Licensing Guidance. So that is being provided to the
5	NRC staff and the working group, Agreement State
6	Working Group for them to disposition and, if they
7	agree, make changes to the guidance with respect to
8	the recommendations that the subcommittee provided.
9	And then after the guidance has been
10	finalized, a memorandum should be distributed to the
11	ACMUI to inform you of how they dispositioned your
12	recommendations.
13	So this will stay open until 1) the
14	guidance comes out; and 2) the memorandum is provided
15	to the ACMUI.
16	CHAIRMAN PALESTRO: Thank you.
17	MR. EINBERG: Excuse me, Dr. Palestro.
18	Sophie, just to lessen your bureaucracy
19	around issuing a memorandum, once we issue the
20	licensing guidance, is there any reason that this
21	couldn't be closed, rather than waiting for a
22	memorandum?
23	MS. HOLIDAY: Mr. Einberg, this was a
24	recommendation, though not formally captured in the
25	recommendation chart, that came from the ACMUI several
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1	years ago. And they requested a memorandum so that
2	they could know exactly how the recommendations were
3	dispositioned. And because of that, they requested
4	that these items remain open until that memorandum
5	comes to them.
6	MR. EINBERG: I see. Okay, thank you.
7	MS. HOLIDAY: So in my haste to put this
8	up, I did not put any edits that the committee just
9	voted on for the Bylaws Subcommittee. So I am going
10	to have to read from my sticky note. The language you
11	see on this screen is not what I am reading.
12	So item 6 is that the ACMUI endorsed the
13	ACMUI Bylaws Subcommittee report with the caveat that
14	the report be amended to remove the phrase in these
15	instances and to add language about the ACMUI chairman
16	will serve on the subcommittee at the subcommittee's
17	discretion.
18	Additionally, the report will be amended
19	in Section 4.1 to reference the OGE reference that
20	will be provided by the Office of General Counsel.
21	This was unanimously approved by the
22	ACMUI. The motion was put forth by Dr. Dilsizian and
23	seconded by Ms. Martin. However, it should be noted
24	that Dr. Palestro abstained from the vote so that his
25	vote would not present as a conflict of interest.
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1	Did I accurately capture the committee's
2	recommendations?
3	Yes, Dr. Schleipman.
4	MEMBER SCHLEIPMAN: I think you missed
5	that we were removing the prior addition of spelling
6	out the financial conflicts of interest.
7	MS. HOLIDAY: Yes, you are absolutely
8	right. Yes, you are correct.
9	So with that, does the committee agree?
10	Okay.
11	Another item not captured on here was that
12	the NRC staff agreed to add language specifically
13	about the conflict of interests in our opening remarks
14	at every ACMUI meeting.
15	Does the committee agree? Thank you.
16	Another item not captured on here I'm
17	sorry. Oh.
18	Another item not captured on here is that
19	the ACMUI recommended that the NRC staff invite the
20	NNSA to present at the fall 2019 ACMUI meeting to
21	review its plans for isotope utilization in the United
22	States.
23	Does the ACMUI agree?
24	CHAIRMAN PALESTRO: Yes.
25	MS. HOLIDAY: Thank you and I will turn it
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1	back to you, Ms. Jamerson.
2	MR. EINBERG: Ms. Jamerson and Ms.
3	Holiday, can we add a column or can we have an action
4	item to add a column to this table with a target date
5	for completion?
6	MS. HOLIDAY: Yes. Does that need to be
7	made a motion or captured?
8	MR. EINBERG: I think we discussed it or
9	the ACMUI members discussed it. We committed to that.
10	So I'm not sure if there needs to be a motion or not
11	but I think that would be a useful item for tracking
12	these items.
13	CHAIRMAN PALESTRO: Rather than debating
14	whether we need a motion, why don't we just make one?
15	This way, it is definitive.
16	So can we have a motion to add an extra
17	column on our recommendations and action items that
18	will include the anticipated date of completion? Is
19	that correct, sir?
20	MR. EINBERG: That's correct.
21	CHAIRMAN PALESTRO: Okay.
22	Mr. Ouhib?
23	MEMBER OUHIB: Yes, I make the motion.
24	CHAIRMAN PALESTRO: Second?
25	(No audible response.)
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1	CHAIRMAN PALESTRO: Any discussion?
2	All in favor?
3	All right, any opposed?
4	Thank you.
5	MS. HOLIDAY: So point of clarification.
6	Is this a target date of completion for NRC staff
7	action?
8	MR. EINBERG: Yes.
9	MS. HOLIDAY: Thank you. So, for the
10	record.
11	MS. JAMERSON: Also not listed on this is
12	Dr. Palestro formed a new subcommittee. The charge:
13	for improving ACMUI's institutional memory.
14	Dr. Schleipman is the chair. Other
15	subcommittee members include Dr. Schleipman as the
16	chair, Ms. Shober, Ms. Weil, Dr. Ennis, Dr. O'Hara,
17	and Kellee Jamerson as the NRC staff resource.
18	Does the ACMUI agree?
19	CHAIRMAN PALESTRO: Yes.
20	MS. JAMERSON: And the last item is the
21	ACMUI tentatively scheduled its fall 2019 meeting for
22	September 11th and 12th, 2019. The alternate date is
23	September 10th and 11th, 2019.
24	Does the ACMUI agree?
25	Okay, this concludes my administrative
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1	closing.
2	MEMBER OUHIB: Kellee, when do you
3	anticipate to have a final date for the meeting
4	between the two?
5	MS. JAMERSON: By next month.
6	CHAIRMAN PALESTRO: All right. Are there
7	any other items, Committee? No.
8	Just before we adjourn, just to remind
9	especially the new members, and obviously to help a
10	couple of you with the hotel rooms, but I would
11	suggest that you make your reservations ASAP. I
12	learned the hard way for my first meeting and since
13	then, as soon as this meeting ends, I go and make my
14	reservations for both meeting dates and then cancel
15	the one that we're not going to use.
16	So all right, with that, the meeting
17	concludes. It is adjourned. I thank you all and we
18	will see you again in September.
19	(Whereupon, the above-entitled matter went
20	off the record at 2:13 p.m.)
21	
22	
23	
24	
25	
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