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on the Medical Uses of Isotopes

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UNITED STATES OF AMERICA
NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

+ + + + +

FALL 2018 MEETING

+ + + + +

FRIDAY,

SEPTEMBER 21, 2018

+ + + + +

The meeting was convened in the
Commissioner's Hearing Room, One White Flint North,
11545 Rockville Pike, Rockville, Maryland, at 8:30
a.m., Christopher J. Palestro, ACMUI Chairman,
presiding.

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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

JOHN H. SUH, M.D., Member

LAURA M. WEIL, Member

PRESENT VIA TELECONFERENCE:

PHILIP O. ALDERSON, M.D., Former ACMUI Member

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NRC STAFF PRESENT:

DOUGLAS BOLLOCK, NMSS/MSST/MSEB, Designated

Federal Official

RUSSELL CHAZELL, SECY/RAS

SAID DAIBES, NMSS/MSST/MSEB/MRST

MARC DAPAS, NMSS

LISA DIMMICK, NMSS/MSST/MSEB/MRST

CHRISTIAN EINBERG, NMSS/MSST/FSTB

SOPHIE HOLIDAY, OE/EB

DONNA-BETH HOWE, NMSS/MSST/MSEB/MRST

KATIE TAPP, NMSS/MSST/MSEB

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CONTENTS

Special Presentation to Dr. Suh.....5

Dr. Suh's Thoughts on Leaving ACMUI.....8

Special Presentation to Dr. Alderson.....15

Dr. Alderson's Thoughts on Leaving ACMUI.....18

Y-90 Microspheres Brachytherapy Licensing
 Guidance.....26

Compounding of Sterile and Non-Sterile
 Radiopharmaceuticals.....66

Medical Team Highlights.....89

Open Forum.....104

ACMUI Subcommittees, NRC staff, NRC management:
 How the Team Works Under FACA.....128

ACMUI Subcommittees, Subcommittees Membership,
 the same ACMUI Chair.....197

Administrative Closing.....201

Adjourn.....211

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P R O C E E D I N G S

8:42 a.m.

1
2
3 CHAIRMAN PALESTRO: I'll call the meeting
4 to order. Yesterday we began by introducing new
5 members to our committee. Today we come to the
6 opposite side of the coin and we say goodbye to two
7 individuals who are not only stalwart members of this
8 committee, but far more importantly, have become our
9 very good friends.

10 And so at this time, I'd like to turn the
11 meeting over to Mr. Marc Dapas, who is the Director
12 of the Office of Nuclear Materials, Safety, and
13 Safeguards. Mr. Dapas.

14 MR. DAPAS: Thank you, Dr. Palestro. I
15 apologize for being late. The Metro didn't
16 cooperate. I have to say it feels a little peculiar
17 sitting in this seat. It's normally reserved for the
18 Chairman of the NRC when she has a Commission meeting
19 with us. So no delusions of grandeur here.

20 Well, first and foremost, it's a great
21 opportunity to acknowledge the service on the
22 Advisory Committee for the Medical Uses of Isotopes
23 of Dr. Suh. He has served on the ACMUI since October
24 of 2010, and he was renewed for a second term in 2014.

25 Dr. Suh has demonstrated expertise in the

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1 field of radiation oncology, especially in gamma
2 knife radiosurgery. In fact, he served as Chair of
3 the Subcommittee on physical presence requirements
4 for the Leskell gamma knife icon, and as well as the
5 gamma knife Perfexion and the Leskell gamma knife
6 Icon draft licensing guidance Revision 1. I hope
7 that got that correct.

8 But we much appreciate the expertise that
9 you were able to provide in supporting that particular
10 subcommittee. He also served on the medical event
11 reporting for all modalities except for permanent
12 implant brachytherapy. And with respect to chairing
13 this particular subcommittee, Dr. Suh provided
14 particular expertise and input to help the Committee
15 in their deliberations.

16 During the time that Dr. Suh has been on
17 the ACMUI, the staff has benefitted from his expertise
18 in a number of high priority issues, including
19 permanent implant brachytherapy, as reflected in the
20 subcommittee that you chaired.

21 The hormesis and linear no threshold
22 petitions for rulemaking. The analysis of yttrium-
23 90 microsphere brachytherapy medical events. A
24 review of NRC's medical use policy statement. And
25 then revisions to Nureg 1556, Volume 9, consolidated

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1 guidance about materials licensees, program-specific
2 guidance about medical use licenses.

3 And most importantly, training and
4 experience requirements, which has been a
5 particularly interesting area of our regulatory
6 engagement, and I know that the Committee is currently
7 involved in evaluating training and experience
8 requirements.

9 Another area that reflects a broad
10 spectrum of views is patient intervention, and I
11 appreciate your engagement in that area. So would
12 like to thank you again for your extensive, eight
13 years of dedicated service here, and we have a few
14 tokens of our appreciation and gratitude that we'd
15 like to present to you.

16 So first, we have a certificate of
17 appreciation that was signed by our chairman,
18 Kristine Svinicki, and it says, In recognition of
19 eight years of service and leadership to the Advisory
20 Committee on the Medical Uses of Isotopes, which
21 resulted in significant contributions to the work of
22 the US Nuclear Regulatory Commission, dated September
23 14, 2018. So congratulations.

24 MEMBER SUH: Thank you.

25 (Applause.)

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1 MR. DAPAS: And then we have to present
2 to you a flag and associated certificate. And this
3 flag was flown over the United States Capitol on
4 August 21 at the request of the Honorable Chris Van
5 Hollen, United States Senator. As stated on this
6 certificate, this flag was flown for Dr. John H. Suh
7 on the occasion of his completion of eight years of
8 service on the ACMUI. So here, congratulations.

9 MEMBER SUH: Thank you very much.

10 (Applause.)

11 MR. DAPAS: And then lastly, we have gold
12 lapel pin here for you, so.

13 MEMBER SUH: Thank you very much.

14 MR. DAPAS: Thank you again for your
15 service.

16 (Applause.)

17 MEMBER SUH: Thank you very much. So,
18 and I was reflecting a little bit about what to say
19 last night and I thought I'd get some inspiration by
20 trying to watch the Cleveland Browns win their first
21 football game, which they did, so. So the city of
22 Cleveland may ask me to return again to get some wins.

23 But I just want to reflect back on my
24 time here, the eight years on the Committee. And
25 when I think about the ACMUI Committee and what the

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1 NRC represents, it's obviously a really important
2 committee. And I don't think I understood what this
3 committee represented until a few years into being
4 part of the Committee.

5 And you know, I was looking at the website
6 last night about what the ACMUI represents. It
7 represents the important role of providing policy and
8 technical issues in the regulation of the medical
9 uses of isotopes and diagnosis and therapy. So
10 that's a very daunting task for this committee.

11 And one of the things that I've really
12 had the pleasure over the past eight years is to
13 really work with wonderful people. This is a very
14 diverse group with various different levels of
15 expertise, some different personalities as well. But
16 at the end of the day, we all get, work together for
17 the common good for the patient, for the public.

18 And at the same time, not imposing on the
19 practice of medicine. Which if you think about it,
20 those three Ps, it's really hard to balance all that,
21 right. Public, patient, and then also the practice
22 of medicine. I think it's very, can be difficult at
23 times.

24 With this subcommittee, the committees
25 that I've had an opportunity to work on have a done

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1 a wonderful job with that. I want to take this
2 opportunity to thank a few people. I see Chris
3 Einberg there.

4 I remember interviewing with Chris, I
5 think it was in 2009. I wasn't sure if I was the
6 right person for the job, because they said, well, we
7 need a gamma knife expertise. I said, well, I can
8 do gamma knife. The other stuff about policies and
9 about regulation, I wasn't sure I was the best person
10 for that. But you know, like anything in life, you
11 learn about what those things mean.

12 I also want to thank Doug Bollock for his
13 leadership and the medical staff, and also the other
14 wonderful people here on the medical staff. It's
15 nice to see Ashley, who helped introduce me to how to
16 sign on and get on travel and get reimbursed, and
17 then followed by Sophie Holiday, who did a wonderful
18 job as well. So I want to thank them.

19 I also want to thank Cindy Tomlinson from
20 ASTRO, who I've gotten to know very well through the
21 years in terms of some of the physical process
22 requirements and other medical events requirements we
23 were trying to do within the Subcommittee.

24 So I'm going to leave with a few thoughts
25 here in terms of my thoughts in serving the ACMUI. I

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1 would really encourage the Committee to continue its
2 excellent work in terms of medical events.

3 I'm a very staunch advocate for quality
4 and safety, and I think it's really important that
5 this committee continues to remember that quality and
6 safety really needs to be a number one priority for
7 this committee. So I would really encourage each and
8 every one of you to continue that.

9 The other thing I would also mention is
10 I think as the Committee, it's also important to share
11 best practices. I think sometimes, and I'll be very
12 honest with you, before I became a member of the
13 ACMUI, I didn't know what this acronym stood for.
14 Which, maybe it's part of my ignorance, but I think
15 it's something where I think we need to do a better
16 job in of promoting what the ACMUI represents and
17 also the important role that it has.

18 Safety culture is also another area I
19 think we can do some good in terms of safety culture.
20 I think as we heard yesterday from Ron Ennis, the
21 fact that we don't do timeouts universally on every
22 patient who undergoes any diagnostic or therapeutic
23 procedure in radiation is something that needs to
24 change. I think that's hopefully something that
25 continued to be messaged as well.

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1 There's also a clear need for data as
2 well. I think sometimes in our deliberations we ask,
3 you know, what's the numerator, what's the
4 denominator. It would be nice, moving forward, if
5 we really had true numbers in terms of what the
6 numerator is as far as the denominator.

7 And last point I want to make is I think
8 it's wonderful that the ACMUI is reaching out to the
9 professional societies. I had the opportunity to
10 give a brief presentation to ARRO, which is the
11 Association for Residents in Radiation Oncology. I
12 think it opened their eyes in terms of what this
13 committee does, the important work it does, how
14 quality and safety really ties in to policies as well
15 as regulations as well.

16 So I'd end by thanking everyone who I've
17 the association of developing very keen friendships
18 with. I hope to keep in touch with many of you, and
19 thank you very much.

20 (Applause.)

21 CHAIRMAN PALESTRO: John, on behalf of
22 myself and of course the entire ACMUI, I'd like to
23 thank you for all that you've done. And it has been
24 a delight working alongside you. I know that for
25 family reasons you oftentimes are in the New York

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1 metropolitan area, and by all means, if you have time,
2 stop by. The door is always open, look forward to
3 seeing you.

4 MEMBER SUH: Okay, thank you.

5 MEMBER ENNIS: I've really enjoyed
6 working with you and getting to know you. And
7 obviously being a great resource as to radiation
8 oncologist on the Committee. And my only hope is
9 that we can continue to work together and stay in
10 touch.

11 (Off-mic comments.)

12 MR. DAPAS: I did want to just offer that
13 I do regret that I haven't had the opportunity to
14 interact with you more frequently.

15 But I do very much appreciate the work of
16 the ACMUI and the considered thought that you provide
17 and the suggested input that you provide to the NRC
18 staff as we're trying to determine what is the best
19 regulatory approach in dealing with a number of
20 challenging medical issues.

21 I mentioned training and experience.
22 Patient release is another area that there is a broad
23 spectrum of stakeholder views, and I know that my
24 team very much values the input that all of you
25 provide as you give very considered and deliberative

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1 thought to those challenging issues. So thank you
2 on behalf of the NRC staff.

3 And I appreciate what you said, Dr. Suh,
4 about the support that you did receive from the staff
5 in helping you be successful in your role in the
6 Committee, so thank you.

7 CHAIRMAN PALESTRO: Dr. Alderson, are you
8 on the line yet?

9 MEMBER ENNIS: Chris runs such efficient
10 meetings we're always ahead of schedule.

11 MR. DAPAS: The agenda said nine o'clock,
12 correct? Sure.

13 CHAIRMAN PALESTRO: John, this isn't
14 really an ACMUI topic, but you brought up the
15 Cleveland Browns winning.

16 MEMBER SUH: Is this being transcribed?

17 CHAIRMAN PALESTRO: It seems only fitting
18 that they would beat the Jets. If there is a team
19 who, there is no team more successful at figuring out
20 how to lose than the New York Jets.

21 MEMBER SUH: I should be very careful
22 what I say, because there could be someone from, well,
23 when you go two seasons without winning a game, it's.
24 But I'm glad that a New Yorker has admitted that, so.
25 Since there are a few New Yorkers around this table,

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1 so that's good.

2 MR. DAPAS: Oh, well, I enjoyed that Red
3 Sox victory last night. I'm from New England, and
4 I'm a diehard Red Sox fan. So clinching the playoff
5 berth in a defeat over the Yankees is a special day
6 for me.

7 MEMBER ENNIS: I'm with you, Marc, but I
8 turned it off when they gave up the grand slam to
9 Stanton. So I missed the comeback.

10 MR. DAPAS: I missed that. I turned it
11 off when it was the eighth inning and Betts hit a
12 home run, I thought, well, that's it, eleven to six,
13 good to go. So I missed a grand slam. Oh, okay.

14 CHAIRMAN PALESTRO: Dr. Alderson, are you
15 on the phone?

16 DR. ALDERSON: I am.

17 CHAIRMAN PALESTRO: Morning, Phil, how
18 are you?

19 DR. ALDERSON: Very good, thank you.

20 CHAIRMAN PALESTRO: All right. Again,
21 at this point, I'm going to turn the session over to
22 Mr. Dapas.

23 MR. DAPAS: Well, thank you. Another
24 opportunity to thank an individual for their service
25 on the ACMUI. Dr. Alderson has served on that

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1 committee since March of 2014. He was renewed for a
2 second term in 2018, at which time Dr. Alderson agreed
3 to stay on the Committee until a replacement member
4 could be selected.

5 Dr. Alderson was appointed Vice Chair of
6 the ACMUI in January of 2015 and was appointed Chair
7 of the Committee in October 2015. He also had the
8 opportunity to brief the Commission during the public
9 Commission ACMUI meetings on several occasions,
10 including March of 2016, where he provided an overview
11 of ACMUI activities and discussed enhancing ACMUI
12 communications.

13 And then he also had the occasion to
14 present and speak before the Commission in April of
15 this year and March of this year, where he again
16 provided an overview of ACMUI activities.

17 During Dr. Alderson's time on the ACMUI,
18 the staff has benefitted extensively from his
19 expertise in regards to, on a number of high priority
20 issues, including the hormesis linear no threshold
21 petitions for rulemaking. In fact, Dr. Alderson
22 served as Chair to the review of the hormesis linear
23 no threshold petitions for a rulemaking subcommittee.

24 He also provided input on review of the
25 NRC medical uses policy statement and Nureg 1556,

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1 Volume 9, which provides consolidated guidance about
2 materials licenses program, specific guidance about
3 medical use licenses.

4 He also has provided input on licensing
5 guidance for radioactive seed localization for non-
6 palpable breast lesions. And then also contributed
7 to a review of the staff's evaluation of training and
8 experience requirements for administering
9 radiopharmaceuticals.

10 At this time, to signify our appreciation
11 for his four years of service on the ACMUI, we do
12 have some things to present. We will be sending a
13 flag to you. I know they say that the check is in
14 the mail here, but I am told that the flag will be
15 mailed to you. I think there was a slight correction
16 that had to be made on the certificate.

17 But that flag was flown over the US
18 Capitol, again at the request of Senator Chris Van
19 Hollen from Maryland.

20 I also have a certificate here signed by
21 our Chairman, Kristine Svinicki. It says, In
22 recognition of four and a half years of service and
23 leadership to the Advisory Committee on the Medical
24 Uses of Isotopes, which resulted in significant
25 contributions to the work of the US Nuclear Regulatory

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1 Commission. And that was signed and dated September
2 14, 2018.

3 And similar to Dr. Suh, we also have a
4 gold lapel pin that we will be mailing to you. So I
5 hope that both of you, Dr. Suh and Dr. Alderson, have
6 a chance to continue to engage perhaps in the future,
7 and you can share your gold lapel pins here.

8 MEMBER SUH: I'll start wearing it right
9 away, so.

10 MR. DAPAS: Thanks. But Dr. Alderson,
11 again, thank you for your dedicated service and the
12 support that you have provided to the Committee as
13 they've deliberated on a number of important issues
14 germane to our regulatory oversight and the
15 beneficial practices of medicine. So thank you.

16 DR. ALDERSON: Yes, you're welcome.

17 (Applause.)

18 DR. ALDERSON: Is it time for me to make
19 a few comments now?

20 CHAIRMAN PALESTRO: Yes, go ahead, Phil.

21 DR. ALDERSON: Thank you. Well, I do
22 want to thank everyone. I really thank the NRC for
23 providing me the opportunity to meet with you today
24 in this long distance approach.

25 When we last spring talked about

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1 potential dates for a meeting this fall, I had no
2 idea that this would fall at the very same time that
3 my daughter and her husband and three grandchildren,
4 who have lived in South America for the last several
5 years, the only time they could visit at St. Louis
6 was this week. It's actually spring vacation week
7 down in Buenos Aires, where they live.

8 So when I found that out, and we had
9 already gone through the decision process of my
10 stepping back from the Chairmanship, I really
11 realized that this ceremony being the primary reason
12 for me being there, this probably wouldn't be a time
13 that I could make it. But I really do appreciate the
14 fact that we were able to set up this call in this
15 way.

16 And I do want to thank all of my
17 colleagues on the ACMUI who have supported the various
18 things that you were just told about that, things
19 that we launched and did during the time that I was
20 with you and was privileged to serve as your Chair.

21 And I wanted to specifically point out
22 two or three people who I think deserve some special
23 recognition. From the NRC side, you know the NRC
24 staffing changes so often, but Sophie Holiday, I hope
25 you're in the room, Sophie. I mean, you have been a

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1 tremendous support to me during my chairmanship.

2 Obviously to my predecessors, and you
3 will be to Dr. Palestro and his team as they move
4 forward. It's been a pleasure to work with you, and
5 I hope that you continue to serve for a long time.
6 The ACMUI needs your support.

7 I wanted to briefly comment on two or
8 three past members of the ACMUI who no longer are
9 with you. It was just a wonderful group that we had.
10 Certainly we all miss Frank Costello. He was a superb
11 state's representative and did great work with us.
12 And always knew how to advise us about how to make
13 things work because he had been such a long-serving
14 person in the NRC and the government.

15 And no one can forget Sue Langhorst. I
16 mean, Sue Langhorst had, it seemed to me, a virtually
17 encyclopedic memory of all the NRC data books. She
18 could quote chapter and verse of regulation and
19 brought great, great insight. I appreciated her
20 energy on the Committee, and it helped us do a lot of
21 things.

22 Pat Zanzonico was my Vice Chair, and Pat
23 brought great expertise to the process. And to all
24 of you, and I'm not going to go through and, I decided
25 I could talk about each one of you who served with,

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1 the time that I was on the chair.

2 But the fact is that then I would
3 inevitably forget to say the right thing about one or
4 more of you, and I really do value each and every one
5 of you. And that's the basic reason I'm sorry that
6 I can't be there today to share these moments with
7 you.

8 I did want to make a couple of comments
9 just about the fact that I know we all respect
10 radiation. We probably wouldn't agree to serve on
11 this committee, or even be eligible to serve on this
12 committee, did we not share that particular outlook.
13 Sophie, this would be the time to have the slide on
14 the screen that I sent to you, so I hope that that's
15 up there now.

16 What you see on the screen is the
17 radiation memorial. They exist in Semey, Kazakhstan,
18 which is a place somewhat remote and unlikely common
19 place for any of you to have traveled.

20 But I had the privilege of traveling
21 there in the spring of 2016 as their guest when we
22 were considering possible associations, affiliations
23 between the medical school that exists there in Semey,
24 one of the five state-sponsored schools in
25 Kazakhstan, and St. Louis University, of which at

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1 that time I was the Dean.

2 So it was official business and the NRC
3 knew I was going there and we cleared all that before
4 I left. It was a very interesting trip. And this
5 was one of the most interesting sites. This very
6 tall and impressive memorial testifies to the fact
7 that the people in Semey unfortunately suffered from
8 radiation. Semey is at the very far eastern tip of
9 Kazakhstan.

10 Kazakhstan's a very large country in
11 central Asia, and at just beyond 20, 30, 40 miles
12 beyond Semey is the western tip of Mongolia, to give
13 you an idea of where this is. This unfortunately was
14 about 60 miles sort of west-northwest of the main
15 Soviet nuclear testing site. During the era of the
16 Cold War in the 50s, the 60s, hundreds of detonations
17 about ground were taking place at that testing site.

18 And the people in Semey and in
19 Kazakhstan, in this area of Kazakhstan, were
20 unfortunately the victims of all those things that
21 happen with fallout, the cancer clusters, the thyroid
22 disease, the birth deformities. And to such extent
23 that they consider themselves a sister city with the
24 cities in Japan that were bombed during World War II.

25 This memorial, this very tall memorial,

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1 shows the atom at the top with its power breaking
2 through the structure of the protective barrier all
3 the way down to the bottom. And you probably can't
4 see exactly what those images are at the very bottom.
5 That is, the sculptor has created the image of a
6 mother on her knees crouched over and trying to
7 protect her baby from the radiation.

8 So it really I think makes an impact on
9 what these people suffered. And other people in
10 other parts of the world, and we all know about
11 Fukushima and Chernobyl and places like that.

12 And even here in St. Louis, we have our
13 own special little problem in this regard, because
14 the Mallinckrodt Chemical Company was one of the
15 agencies of the federal government that agreed to
16 help make materials during the World War II time when
17 the bombs were being created.

18 And when that was over, there was a lot
19 of residual of those materials. Eventually, those
20 materials were moved out to what was then remote St.
21 Louis County and were buried. Now, you couldn't do
22 that today. I mean, there are too many regulations
23 about these things.

24 But in fact these areas, what's called
25 the West Lake Landfill, still do exist, and they have

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1 created all the controversies here in St. Louis
2 because now there are some cancer clusters in an areas
3 called Coldwater Creek where some water comes from
4 areas that might have been some seepage.

5 Well, I'm not going to give you all the
6 details, but the fact of the matter is it's another
7 example of the power of radiation and how we have to
8 always respect that power. And I believe that as
9 members of the ACMUI advising the NRC have to always
10 remember the power of radiation and protecting the
11 public from radiation. That is our primary goal.

12 And yes, there are other goals that have
13 come out as we have now begun to reconsider the
14 educational process, so what really is required for
15 someone to handle radioactive sources. And well,
16 those things are important.

17 But I hope that as we go forward and
18 consider the balance between public convenience and
19 availability of therapies with the issue of radiation
20 safety, I think that we, and I speak really now as a
21 member of the general public because my term
22 officially I think ended yesterday or the day before,
23 I think we have to come down with the ratio favoring
24 radiation safety.

25 And it's that respect for radiation that

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1 I wanted to use with the Kazakhstan memorial to make
2 that point. We just have to keep considering these
3 things and realize that that is our strongest goal.

4 Well, I don't want to belabor these
5 points. I think that the memorial is a very beautiful
6 and interesting testament to what's gone on in
7 Kazakhstan. It was a pleasure, a privilege to be
8 there and to be able to see it.

9 And it's been privilege and pleasure to
10 work with all of you. I certainly think now with Dr.
11 Palestro, Dr. Metter in charge, you have a great new
12 leadership team. I know that the NRC is very engaged
13 with the myriad of problems that we've discussed. I
14 think you're on a good track. And I wish all of you,
15 all of you the best and future success in your
16 important work. Thank you very much.

17 (Applause.)

18 CHAIRMAN PALESTRO: Phil, this is Chris.
19 You know, you and I have known each other now for
20 more than 30 years, and our paths have crossed in a
21 lot of different ways, a lot of different times. But
22 it has always been an honor and a privilege to work
23 with you, for you, and alongside you. And for that
24 I thank you very much. And I wish you the best in
25 the future.

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1 DR. ALDERSON: Thank you very much,
2 Chris, it's been a mutual pleasure.

3 VICE CHAIRMAN METTER: Phil, this
4 Darlene. And I'd also like to thank you for all the
5 guidance you've given me over these past, I don't
6 think I've known you as long as Chris, but I've known
7 you for other societies with the American Board of
8 Radiology and the other different societies we've
9 been in.

10 But thank you very much. You've always
11 been a role model for me, and you've really been a
12 great person to look up to. And thank you, and I
13 wish you the best.

14 DR. ALDERSON: Thanks, Darlene.

15 CHAIRMAN PALESTRO: All right, thank you
16 very much, Phil, it's been a pleasure.

17 DR. ALDERSON: Great, have a great day.
18 Bye bye.

19 CHAIRMAN PALESTRO: All right, we're
20 going to move along now, and the next topic, Dr. Tapp
21 is going to present on Y-90 microspheres
22 brachytherapy licensing guidance. Dr. Tapp.

23 DR. TAPP: Thank you, Dr. Palestro.
24 Today I'm going to talk about an update to the
25 yttrium-90 microsphere brachytherapy licensing

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1 guidance. Next slide, please.

2 I have three topics to cover today.
3 First, I want to talk about the status of the current
4 revision that the NRC and the organization of
5 agreement states are working on, Revision 10 of the
6 licensing guidance. Then I want to talk about an
7 evaluation of medical events associated with the
8 yttrium-90 microspheres that the NRC conducted
9 earlier this year.

10 And then a future project on
11 comprehensive training and an experience evaluation
12 associated with yttrium-90 microspheres licensing.
13 Next slide.

14 So to start, we're going to talk about
15 the current work on updating the licensing guidance.
16 As you may remember, last January we submitted the
17 licensing guidance in the Federal Register asking for
18 public comments. This is the first time we requested
19 public comments on a 10 CFR 35.1000 licensing
20 guidance.

21 In addition, in July, as we all know, the
22 Part 35 rule was finalized and was published, and
23 that is going to become effective in January of this
24 year. So right now the NRC and the Organization of
25 Agreement States Working Group is in the process of

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1 reviewing the public comments that we received from
2 the public comment period and reviewing the final
3 rule to make applicable changes to the licensing
4 guidance. Next slide, please.

5 In the public comments, we received over
6 100 letters from different commenters, 103 of these
7 commenters used the same template letter. So we
8 received about 30 different comment letters from
9 different individuals, from societies, from
10 manufacturers, users, and members of the public.

11 The majority of the commenters commented
12 on the manufacturer training pathway. This is the
13 pathway that allows the manufacturers to provide AUs
14 training to get their status and to become authorized
15 users. This pathway is known as Pathway 2. Next
16 slide, please.

17 The majority of these commenters
18 recommended the retention of this pathway allowing
19 the manufacturers to continue providing this training
20 to future AUs. Their reasoning is that manufacturers
21 have vast experience and can provide consistent
22 training. They can keep up to date with current
23 events and provide status updates quickly.

24 They also, commenters stated that the
25 onsite training that the manufacturers provide to the

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1 entire team at the sites promotes patient safety.
2 And they had concern that there is limited training
3 facilities if the manufacturers were not allowed to
4 come to the sites to provide this training and the
5 AUs had to go to find other AUs. There is public
6 concern that there wasn't enough training facilities
7 for that purpose.

8 For these reasons, again, the majority of
9 the commenters recommended to keep this pathway
10 allowing the manufacturers to provide this training.
11 Next slide, please.

12 Four commenters did recommend removal of
13 Pathway 2. Their reasoning was to be consistent with
14 other modalities, to ensure the trainers are
15 physicians and not manufacturer representative. And
16 one commenter was concerned that there was too strong
17 of an industry push, and then if you removed the
18 manufacturer training, this would support independent
19 physician practice decisions. These are public
20 comments.

21 In addition to the training experience
22 Pathway 2 comments, we received public comments on
23 written attestation, that they also had a comment
24 that there's a new American Board of Radiology Board
25 certificate for interventional radiology, and wanted

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1 to update our guidance to capture that.

2 There were comments on medical events,
3 radiation safety officer training, post-treatment
4 surveys, possession limits, and then other authorized
5 user training requirements. So we received a gamut
6 of comments there, but not as many as the Pathway 2.
7 Next slide, please.

8 So as I mentioned that the NRC and
9 Agreement States are working right now to review these
10 comments, update the licensing guidance, as well as
11 review the rule and make sure we capture any changes
12 in the rule that could affect the guidance. Once we
13 have a final draft, we will provide that to the ACMUI
14 for your review and recommendations.

15 We will also at that time provide the
16 final draft to the regions and the states for their
17 comments, and it will be also some time, because we
18 have to do a congressional review on the guidance.
19 So before it's published, there is some more steps we
20 have to take before the guidance will be final. Next
21 slide.

22 So now I'm going to change topics and
23 talk about the evaluation of yttrium-90 microsphere
24 medical events that the NRC conducted earlier this
25 year. Next slide. This was, the evaluation results

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1 were presented at the Agency Action Review Meeting to
2 the Commission in June of this year.

3 This evaluation was completed at the
4 request of NRC staff after there was concern that
5 there was increase in yttrium-90 microsphere medical
6 events in recent years. Next slide.

7 This evaluation examined three specific
8 areas, the regulatory requirements associated with
9 yttrium-90 microsphere use, use of post-treatment
10 imaging determining dose delivery, and potential
11 licensee performance trends. Next slide.

12 At the conclusion of this evaluation,
13 their recommendations were requiring post-treatment
14 imaging would not recommended. This was something
15 that the ACMUI previously had recommended to the
16 staff, was to not require post-treatment imaging.
17 And there was no change in that recommendation, the
18 staff did not find a need at this time to require
19 post-treatment imaging.

20 There was no negative performance trends
21 or regulatory gaps identified, and it was also
22 identified, getting some information from the
23 manufacturers, that the number of medical events
24 reported have been increasing over time. But this
25 increase is commensurate with the increase in

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1 yttrium-90 use.

2 Yttrium-90 use has been increasing over
3 years, and the medical events have just increased
4 with that number. They have not, the incident rate
5 has stayed the same. Next slide, please.

6 And my final topic I want to talk about
7 today is a comprehensive training and experience
8 evaluation. Next slide. During the public comments
9 that we received, we received numerous comments that
10 stated the manufacturer representatives can provide
11 better training than AUs. So we're allowed, for
12 yttrium-90 you're allowed to either have
13 manufacturers provide training, or AUs train other
14 AUs.

15 As I stated that the majority of
16 commenters wanted to keep this manufacturer
17 representative training, but the commenters went
18 above that and even stated that that training is
19 better than AU training to AU.

20 There also was commenters stating that
21 there is a need for onsite training, that this may be
22 something that needs to be done to promote patient
23 safety. So the Working Group wanted to evaluate this
24 further.

25 And then we have had recent enforcement

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1 actions and inspection insights that show there
2 possible is an AU knowledge gap in written directives
3 ordering medical event evaluation and calibration.
4 So again, the Working Group wanted to look into this
5 further. Next slide, please.

6 The current training requirements are
7 listed in the 10 CFR 35.1000 licensing guide, and
8 this is a recommended pathway for individuals to
9 become authorized users. In this guidance, it has
10 multiple pathways. This is because there's multiple
11 different types of authorized users.

12 There's nuclear medicine physicians,
13 radiation oncologists, and interventional
14 radiologist, who would become users for yttrium-90.
15 So there's different pathways depending on what type
16 of position the individual is.

17 And then they're allowed to either have
18 manufacturer training or AU training to provide the
19 clinical use training. Next slide, please.

20 For radiation oncologists and nuclear
21 medicine physicians, the general requirements are
22 that they meet the standard in 10 CFR 35.390 or 490,
23 and then they have additional training in the use of
24 the delivery system, the safety procedures, and
25 clinical use for the device.

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1 This can be provided again by the AU,
2 which includes three hands-on cases, or from a
3 manufacturer, which includes three in vitro cases and
4 three hands-on cases. Next slide.

5 For interventional radiologist, there's
6 a slightly different pathway. They can either be
7 Board certified or demonstrate that they've had three
8 years of supervised diagnostic radiology experience
9 and one year of supervised interventional radiology
10 experience.

11 This does not have to be an AU-eligible
12 diagnostic radiology experience. This is just they
13 have three years of diagnostic radiology, an
14 experience with use of radiation.

15 They then additionally have to have 80
16 hours of classroom and laboratory training for
17 byproduct material, including yttrium-90
18 microspheres. Next slide.

19 Like the other pathway, they have to have
20 work experience. And this experience, though, can
21 be provided by an AU or a manufacturer representative.
22 And they also have to have the training in the
23 delivery system, safety procedures, and clinical use.

24 Again, similar to nuclear medicine and
25 radiation oncology, this training can be provided

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1 from the AU or a manufacturer representative at this
2 time. Next slide, please.

3 So the NRC and the Working Group may want
4 to look into this further and see if there's any
5 knowledge gaps in these AUs, so anything that maybe
6 we need to look at closer to see if the training needs
7 to change. So right now we're creating an evaluation
8 plan to see how we're going to evaluate this.

9 The Working Group now has proposed doing
10 an inspection temporary instruction to collect more
11 information. As we know when we get medical events
12 in our NMED, sometimes we don't have all the data
13 there to look and see is it related to the training.

14 So we're talking about possibly doing an
15 inspection that we can go out and specifically look
16 at knowledge of the AUs involved in these medical
17 events and AUs for yttrium-90, and then report back
18 so the Working Group can evaluate this and see if
19 there is potentially a knowledge gap.

20 And then this evaluation is definitely,
21 is being separately done from the comprehensive
22 training experience evaluation for
23 radiopharmaceuticals.

24 This was more in response to the public
25 comments and looking further into the question is the

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1 difference in training people are receiving from the
2 manufacturer versus training from an AU to AU. This
3 is separate from the comprehensive training
4 experience that we've been talking about in the past.
5 Next slide, please.

6 The path forward, the Working Group is
7 still continuing on Revision 10, and we plan to issue
8 a draft guidance to the ACMUI in Fiscal Year '19.
9 This is going to be done before we complete the
10 comprehensive training evaluation. We just want to
11 get that out, there's changes that we want to start
12 implementing before we do a further evaluation of the
13 training experience.

14 I think the next slide is the acronyms.
15 Opening it up for questions.

16 CHAIRMAN PALESTRO: Ms. Weil.

17 MEMBER WEIL: Just an informational
18 question. Why is the manufacturer training requires
19 three in vitro cases in addition to three hands-on,
20 while the AU training doesn't?

21 DR. TAPP: So the manufacturer pathway,
22 the individual can do the three in vitro cases first,
23 then be added to a license. And then the
24 representative comes out and they do the three hands
25 on. Whereas AU to AU training, they do everything

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1 up front, and then are issued on a license. And they
2 don't have any more commitments.

3 I don't know.

4 MS. COCKERHAM: This is Ashley Cockerham
5 with Sirtex. Just to answer your question on that,
6 the issue is you couldn't do hands-on training with
7 the product because you wouldn't be licensed to
8 actually possess the product. Does that make more
9 sense? See, at least do a cold run, get the license
10 amendment, and then you can order the product, then
11 you can do the real cases.

12 CHAIRMAN PALESTRO: Dr. Metter.

13 VICE CHAIRMAN METTER: Thank you, Dr.
14 Tapp, for your presentation. I think there has been
15 a question in the past that has been brought up that
16 the manufacturer training pathway, let's say they do
17 the cold runs, the three that they do, and they get
18 on the license, and then they never complete or they
19 don't complete the three hands-on cases.

20 Is there a timeframe, or what do you all
21 plan on looking at that? Because I think that could
22 be a potential, and has been, I believe, a problem.

23 DR. TAPP: As you remember, the draft
24 that went out for public comments has a timeframe
25 associated with it. I believe it was six months

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1 after they were issued on a license to complete their
2 training. There was public comments on that, and the
3 Working Group is evaluating if that timeframe is
4 appropriate.

5 But the draft that went out for public
6 comments did have that, and the Working Group is
7 considering a timeframe to ensure that recentness of
8 training is done before they have patients and they
9 do a patient case. So it's six right now, the draft
10 had six months.

11 VICE CHAIRMAN METTER: So again, being
12 the Devil's advocate in the sense of let's say I did
13 it and didn't do my. What happens to it? Do I get
14 off, do you take me off the license then, or what's
15 the consequences of not completing the training?

16 DR. TAPP: In the draft that went out for
17 public comment, it stated that they would have to
18 have applied to have more training before they could
19 have a patient case. An acceptable example that was
20 provided in the licensing guidance would be one more
21 in vitro case immediately prior to doing a patient
22 case.

23 So that was an example given in the draft.
24 But again, there was public comments on that, so we
25 are evaluating that and it's not final.

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1 CHAIRMAN PALESTRO: Other comments? Dr.
2 Ennis?

3 MEMBER ENNIS: Just a question of whether
4 the Working Group has the ability or has looked at if
5 there's a correlation within the reported medical
6 events and what type of preceptor training was done.

7 DR. TAPP: That's what we're hoping going
8 out and doing a temporary inspection procedure we
9 could provide more information on that. Because
10 right now, NMED does not have that information.

11 CHAIRMAN PALESTRO: Dr. Dilsizian.

12 MEMBER DILSIZIAN: Thank you, Doctor.
13 So in the spirit of the medical events under your
14 slides of evaluation of Y-90 microspheres, it says,
15 Requiring post-treatment imaging was not recommended.

16 So you know, we do post Y-90 treatment
17 imaging, because all times, because the only way you
18 evaluate whether it was a misadministration, whether
19 it was a radio, a Y-90 microspheres going to the
20 stomach or the lungs is the only way, can only
21 evaluate that by post-treatment imaging.

22 So I guess I wanted to know what the
23 thought process there was. And is this an official
24 not recommended, because we seem to do it all the
25 time in our institution.

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1 DR. TAPP: First, I should clarify that
2 it's not recommended to include in, as a regulatory
3 requirement. We're not saying it's not recommended
4 to do, it's just not a regulatory requirement.

5 That position was made, or that decision
6 was made based on an ACMUI recommendation to us that
7 the current post-treatment imaging does not have, is
8 not quantitatively accurate enough yet where it's the
9 standard of care.

10 MEMBER DILSIZIAN: I mean, I just I would
11 like to hear my colleagues' comments, because the
12 only way you would know whether you delivered the
13 dose correctly in the right organ, the right lobe, is
14 to do imaging. Otherwise, it's leap of faith. I
15 just don't understand what the discussion was, at
16 least I wasn't part of that.

17 DR. TAPP: And to my understanding as to
18 the Working Group is the catheter placement and
19 verifying the catheter is in the correct place at the
20 time is really the only thing currently under control
21 of the medical team. And then for one of the
22 manufacturers is to continuously do the contrast and
23 check on that.

24 But the catheter placement is what is in
25 the authorized user's control. So we do require them

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1 to know that they put the catheter in the right place,
2 and then to do a performance base. It's up to the
3 institution to determine how they want to verify that
4 they have put the material in the right spot.

5 MEMBER DILSIZIAN: No, I understand all
6 of that. I just wanted to say that if we're going
7 to be monitoring medical events, there's no way we're
8 going to be able to monitor medical events if we don't
9 do imaging, that's all. I mean, from a regulatory
10 perspective.

11 CHAIRMAN PALESTRO: Yeah, this is Dr.
12 Palestro. I just want to echo Dr. Dilsizian's
13 comments. I mean, there are certain medical events
14 that you can monitor, for example, if the activity
15 doesn't make it into the patient for one reason or
16 another.

17 But catheters do slip from time to time,
18 and the potential for administering the activity to
19 the wrong organ certainly exists. And without the
20 post-treatment imaging, you're not going to know that
21 until such time as the radiation complications
22 develop.

23 DR. TAPP: I think Doug.

24 MR. BOLLOCK: This is Doug Bollock, NRC.
25 I can address a little bit further what Dr. Tapp has

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1 already spoken about. So we are, we do recognize
2 that without some sort of post-treatment evaluation,
3 as Dr. Palestro said, we're limited in how we know if
4 something went wrong.

5 But as Dr. Tapp said, the assurance that
6 the procedures went correctly is the catheter
7 placement. And so that is, that's the assurance
8 under 3541 that you've followed the procedure, that
9 it's gone correctly.

10 As she also stated, the post-treatment
11 imaging is not standard practice to get the
12 qualitative information. So for we understand with
13 microsphere treatments, microspheres could go to
14 other parts, and it could be one or two percent.

15 And it could, any standard PET I think is
16 a, a standard PET may just, it'll show in other areas,
17 though it's very, very low levels, and you can't
18 quantify that to know whether it was just part of the
19 treatment, or was it the catheter moved, you didn't
20 get the full--

21 DR. TAPP: I should clarify, he said PET
22 but its standard SPECT would not provide that.

23 MR. BOLLOCK: Sorry, yeah. So it's for
24 standard SPECT that you may not get that. But again,
25 we do recognize that, and this is why we ask that the

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1 question came in and we looked into it. Should we
2 consider making it a regulatory requirement to do
3 that post-treatment imaging?

4 Now, again, we still relied on our
5 initial review, which is catheter placement assures
6 that the treatment is going to get, the patient is
7 going to get the treatment as it's intended. That
8 with the verifying the activity, you know, they got
9 the activity, the dose that was intended by monitoring
10 the vials and checking the waste because that'll
11 assure that the treatment is correct.

12 With the whether or not there's a scan
13 afterwards would not prevent an event from occurring.
14 Now, we do recognize it doesn't help us in
15 understanding then what happened or not.

16 MEMBER DILSIZIAN: No, no, I just want
17 to address this. One this is to place a catheter, I
18 understand the procedure. But remember, what we're
19 following is the way the microsphere goes. The cath
20 is in the right place. However, if the dose went to
21 the lungs and patient has fibrosis, lung fibrosis or
22 has stomach ulcer, you would not know that. The
23 catheter is in the right place.

24 Technically, it was the right thing, but
25 the physician didn't do the right dosing, perhaps, or

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1 it went to the wrong. So patient management and
2 adverse events have something to do beyond just the
3 catheter or where the radiotracer is going.

4 MR. BOLLOCK: And we recognize that.
5 There are other patient follow-up, and this where we
6 don't want to get too far into the practice of
7 medicine and what the doctors determine what the
8 follow-up will be to determine those type things.

9 DR. TAPP: As of right now, we leave it
10 more performance-based. So it's up to the
11 institution based on what instrumentation they have,
12 if they're going to do it during a follow-up, or if
13 they're going to do it with an imaging system, or
14 different methods that I don't know of right now off
15 the top of my head. Such the two I know.

16 But I will say the staff's evaluation was
17 really relying on the 2013 recommendation from the
18 ACMUI. There has been updates to imaging, as we know
19 it's increasing, especially for yttrium-90 post-
20 treatment imaging. So if there was a change here
21 that we would take a different look at it. I do want
22 to focus most of our evaluation was focused on the
23 report from the ACMUI in 2013. So it's.

24 CHAIRMAN PALESTRO: And Dr. Tapp, I guess
25 if I understand you correctly, and what Mr. Bollock

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1 is saying is that even though we can do the post-
2 treatment imaging, and even though we may appreciate
3 the fact that the activity has gone to the wrong organ
4 or organs, there's no real way to quantify the amount
5 of activity with SPECT imaging, and therefore you
6 really can't determine whether or not it's a medical
7 event. Is that correct, is that fair to say?

8 DR. TAPP: There are currently, there are
9 imaging capabilities out there and new software that
10 can quantify that is coming out in research and it's
11 coming out now to clinical practice. But with
12 standard SPECT, it is not quantitative.

13 MR. PALESTRO: Mr. Ouhib.

14 MEMBER OUHIB: Yeah, there is some work,
15 but I think the dosimetry is not quite accurate. I
16 think this part should be left to the practice
17 guidelines, in my opinion, and that's where it fits
18 properly.

19 You know, I was looking at requiring
20 post-treatment imaging was not recommended, and I was
21 like say, maybe it should be not mandatory, but
22 suggested or something like that. I think that would
23 be probably much better, in my opinion.

24 CHAIRMAN PALESTRO: Dr. Metter.

25 VICE CHAIRMAN METTER: Yes, thank you for

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1 your comments. I understand the ACMUI reviewed this
2 in 2013, and that's been five years now. And
3 initially when Y-90 came out, it was usually to whole
4 liver. I'm not sure what other institutions do, but
5 at our institution we do a fair number of these, and
6 do split livers. And as far as a pretherapy imaging
7 with MAA, is that a regulatory requirement? Or a
8 suggestion?

9 DR. TAPP: It is not a regulatory
10 requirement. It is, however, we, with our medical
11 event reporting conditions that are in the licensing
12 guidance, we do not require reporting of lung
13 shunting, if a pretreatment evaluation is done in
14 accordance with manufacturer recommendations, which
15 would be the pretreatment MAA.

16 VICE CHAIRMAN METTER: So I mean in the
17 sense of I'm not sure what other institutions do, but
18 we generally treat one lobe, wait a month, and then
19 treat the next lobe.

20 And it's interesting, because the
21 pretherapy scanning is only done for the whole liver,
22 and we've seen at our institution is that let's see
23 pretherapy was less than ten percent and we do do
24 post-treatment therapy imaging with planar, which you
25 can kind of quantitate or generally get a quantitative

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1 with the geometric mean, the thing is that we did see
2 significant lung shunting post-therapy after the next
3 lobe was treated.

4 So I think imaging, I like the idea.
5 Maybe information, a guidance in regarding to not
6 making it regulatory, but information guidance
7 regarding that, you know, would be helpful.

8 DR. TAPP: And I, technically I have seen
9 that and it is, post-treatment imaging is coming up
10 and is there. Are you recommending that the NRC do
11 a regulatory guidance?

12 VICE CHAIRMAN METTER: No, well, just an
13 information sort of thing, and the reason is it did
14 help us. Because we, as far as the patient's health,
15 we'd have to follow her lung functions if she was
16 being compromised and things like that. So it does
17 help in the management of care, which we're not
18 involved with.

19 But I think as far as maybe an information
20 sort of thing is that that can be, that would be
21 helpful in future managements for the patient or
22 something like that. But not making in regulatory
23 sort of thing.

24 CHAIRMAN PALESTRO: I just wanted to go
25 back to Mr. Ouhib's comment about the phrase not

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1 recommended. It almost sounds, that phrase, as if
2 you're recommending against performing. And I think
3 maybe a better choice of words would be something
4 like is not required.

5 DR. TAPP: It would have been a better
6 choice of words, I apologize.

7 CHAIRMAN PALESTRO: Mr. Ouhib.

8 MEMBER OUHIB: Yeah, it might be a good
9 analogy here, but when you look back to prostate
10 brachytherapy implant, and so you know, when you think
11 about the catheter and you think about the needles
12 sort of side by side, you're putting the needles right
13 into the target, into the prostate.

14 Now, you have seed migrating. You think
15 about, you know, the same thing happening, is that a
16 medical event or not? Obviously not, as long as you
17 have put your needles or your seeds into the target.
18 Now, you have no control after that, basically.
19 That, what's going to happen is, you know, is out of
20 the authorized user's hands, basically.

21 So I think this is really, in my opinion,
22 this is why this is very appropriate. My
23 recollection, and I don't want to be held on this, is
24 that in the practice guideline, I think the imaging
25 was highly recommended.

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1 This is, and again, I hate to say it, but
2 this is one item that maybe I'll leave it till later,
3 is that there's got to be a work between what we do
4 and what the practice guidelines are recommending.
5 That they'll be sort of like consistent.

6 In other words, in putting something in
7 here on yttrium-90 that is not consistent with what
8 the practice guidelines are from ASTRO ACR and so on
9 and so forth, I think we need to sort of sink that so
10 we're not saying that absolutely makes no sense.

11 CHAIRMAN PALESTRO: Mr. Sheetz.

12 MEMBER SHEETZ: We do both types of
13 microspheres at the University of Pittsburgh. We do
14 post-therapy imaging. The imaging is qualitative,
15 not real diagnostic. You're utilizing bremsstrahlung
16 imaging or bremsstrahlung photons.

17 Also, too, there is always a preplanning
18 study that's required by the manufacturer on the FDA
19 package insert with technitium-99 MAA. And so that's
20 for mapping. The mapping is done with MAA particles,
21 the therapy is done with 35 micron microspheres.
22 They have different flow dynamics.

23 And so we have actually seen, you know,
24 they don't always match where the MAA landed and where
25 the microspheres end up. And you see differences

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1 from the day of planning to day of treatment where
2 the dynamics and flow is somewhat different.

3 Catheter placement is identical, and all
4 of a sudden, you know, from the planning study, it
5 went in one direction to one area of the lobe and
6 then on the day of therapy it goes in another.

7 So I would not want that to be a judgement
8 on a medical event. And I think from the ACMUI
9 subcommittee, they recognized this, that if the
10 appropriate planning study is done to look for lung
11 shunting and extra-hepatic flow, and you position the
12 catheter at that same location for the therapy, then
13 that is appropriate in that any variation from that
14 point forward on distribution to different areas of
15 the liver or extra-hepatic that were not recognized
16 would be something out of the control of the licensee.

17 And so I think it's important to do post-
18 therapy imaging to gather further information. We
19 have seen where it did not go to the appropriate area,
20 and so then we brought the patient back in several
21 weeks to treat again to try to get microspheres to
22 the appropriate area, but I don't think that
23 represents an error on the licensees. So I just
24 wanted to clarify that.

25 CHAIRMAN PALESTRO: Ms. Cockerham, I know

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1 you wanted.

2 MS. COCKERHAM: Yes, thank you, just to
3 address Dr. Metter's question earlier. There's
4 actually a part of in Sirtex, for our proctoring
5 program, we actually surveyed our proctors a couple
6 of years ago just when I had joined for that mapping
7 piece. Because as a company we actually believe that
8 planning is critical.

9 And there was confusion because we would
10 go out and proctor three times, but sometimes one of
11 those proctoring sessions would be a mapping, because
12 it is very important. And when we surveyed our
13 proctors, they unanimously said, yes, we think that
14 we should be there and we should be doing, you know,
15 peer to peer, MD to MD evaluation of that mapping.

16 And so that is actually built into our
17 process. So one of our proctored cases may very well
18 be one of those planning treatments, and then two
19 additional cases would be for the dose
20 administrations.

21 And then we would have a manufacturer
22 representative being the actual sales rep doing the
23 third case for the purposes of AU, with the caveat
24 that our MD physician has already signed off after a
25 mapping and two dose administrations, if that makes

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1 sense. So that was my first comment.

2 The second one was, and Mr. Sheetz
3 already kind of talked about this for the post-implant
4 imaging, it was just February of this year, the MIM
5 software was FDA-approved, which is the software that
6 would do quantitative analysis specifically for Y-90.
7 They have a Sure Plan.

8 So if we're looking at, you know, what is
9 the status of is everyone doing post-implant imaging,
10 sure, but how great is the technology? There's just
11 now an FDA approval for that actual software to do
12 the quantitative analysis. So MIM has theirs with
13 SurePlan, and then there's a second one, drawing a
14 blank right now, RapidSpheres.

15 So those two are just coming out. We're
16 starting to see those incorporated into our
17 facilities, and they're piloting them, and they're
18 starting to use them. But that's at the big academic
19 centers.

20 And so this, you know, Y-90 is used across
21 the industry in all different types of settings, it's
22 not just in the big academic centers. So we're just
23 starting to see really the dosimetry piece step up.

24 CHAIRMAN PALESTRO: Any other comments
25 or questions? Mr. Ouhib?

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1 MEMBER OUHIB: Yes, I have two questions,
2 actually, for Dr. Tapp. Is that, what is the target
3 date for the draft for Fiscal Year 2019?

4 DR. TAPP: We're hoping for this winter,
5 for the draft to ACMUI.

6 MEMBER OUHIB: This winter, that means
7 2000 -- oh, I see, okay. The other question is
8 regarding the data that you stated that there's an
9 increase in the use of yttrium-90, and this is what.
10 It would be great to sort of dissect that data a
11 little bit more and see is there a correlation really
12 users an event?

13 Or is it manufacturer issues an event or
14 whatnot? I think that would be very, very helpful
15 to see that, where is this coming from. It's just a
16 thought.

17 DR. TAPP: Okay, thank you.

18 CHAIRMAN PALESTRO: Mr. Sheetz.

19 MEMBER SHEETZ: On a different topic, I
20 would like to strongly recommend retention of the
21 manufacturer training pathway. I think it's very
22 important. Both companies have developed teams and
23 programs, both technical personnel and physicians.
24 And they come in and they train the entire Y-90 team,
25 it's not just the authorized user. Again, it's

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1 nuclear medicine technologists, medical physicists,
2 interventional radiology personnel.

3 And so they take the time to make sure
4 everybody is trained in that. They also all have
5 physicians that come in. They may not be authorized
6 users, but they do have that physician to physician
7 contact. I have no vested interest in any of the Y-
8 90 manufacturers, go on record as saying that.

9 But I've seen both their training
10 programs. One offers a one-day course, as center of
11 excellence course. The other company I think is
12 developing one. So I would not want to see this go
13 away and have another AU rely on just an AU for that
14 facility to provide all of this training. Thank you.

15 DR. TAPP: Thank you.

16 CHAIRMAN PALESTRO: Dr. Martin.

17 MEMBER MARTIN: I would just reiterate I
18 think what Mr. Sheetz said is very important to
19 realize. It is training the team, and I think that's
20 what gets missed when you just do authorized user to
21 authorized user. There's a lot more to training the
22 team. You need to train the physicist and you need
23 to train the support, the nuclear medicine
24 technologist.

25 But the whole group needs to be trained,

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1 and not just one authorized user to the other.

2 CHAIRMAN PALESTRO: Mr. Sheetz.

3 MEMBER SHEETZ: Additionally, as
4 yesterday we demonstrated that the majority of the
5 medical events with the Y-90 microspheres is the
6 residual activity in the delivery apparatus, and
7 that's another item that the manufacturers will, in
8 the three simulated cases, go over the delivery
9 apparatus and how it works and how it functions,
10 potential errors that can be, you know, that can
11 occur.

12 And so that type training on the device
13 setup and operation is invaluable.

14 CHAIRMAN PALESTRO: Mr. Ouhib,

15 MEMBER OUHIB: Yeah, I like the ask a
16 question Dr. Dilsizian about this, is how often when
17 doing such a procedure you verify the shunt prior to
18 the procedure itself? In other words, there's been
19 a report where something was done a week ago, two
20 weeks ago, and then the second time that things were
21 sort of different.

22 So is that standard procedure, or does
23 that vary from one place to another, repeating that
24 shunt evaluation?

25 MEMBER DILSIZIAN: So we routinely do

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1 MAAs to determine what the percent of lung is.
2 Obviously the interventional radiologist accordingly
3 modifies the dose. And there are other decisions
4 that they make, which is in the past they used to be,
5 you know, right lobe of the liver first, then left
6 lobe, now it's more targeted, even segments of the
7 liver.

8 And so that's where my question comes in.
9 Because in the past it was more left then right, and
10 the error of left and right is, you know, really tough
11 to make. But now we're saying we're going to target
12 specific segments.

13 If that's the goal, and that's the dose,
14 do we really get there? That was my question. So
15 we routinely do Y-90 PET imaging afterwards, truly
16 fantastic, you know, PET CT imaging, which is really
17 a positron emitter and we get nice images.

18 And again, specifically says this is the
19 segment it went to. Didn't go to the stomach, or the
20 dose modification didn't impact the lungs. I mean,
21 at least clinically we seem to be very in favor of
22 this.

23 I understand it may not be regulatory, I
24 got you that. I think that that may be medical
25 decision, and I'm okay with that. I think we've kind

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1 of said about the art of medicine and we shouldn't
2 really have NRC interfere with that.

3 But from the medical events perspective,
4 I was just trying to get to the point, was that if
5 we're going to follow up Y-90 and the training and
6 whether it's doing the right thing or not, we really
7 don't, we're not going to have the data. That's what
8 I was saying.

9 I wasn't suggesting NRC should get
10 involved, but I'm simply saying that it's really tough
11 to know with medical events perspective whether this
12 is working or not if we don't do imaging. That's
13 all.

14 CHAIRMAN PALESTRO: Yes, sir.

15 MR. PETERS: Hi, Mike Peters, American
16 College of Radiology. Just a quick process question
17 for Katie. You mention the revisions going to ACMUI
18 for review in winter. Is it then going to be released
19 in a draft revision format for public comment after
20 that, or is it going to be released in final revision
21 form and effective immediately?

22 DR. TAPP: It will likely be released in
23 final. If there's significant changes, it's possible
24 we will have a delay implementation. If they're
25 relatively little changes, it would probably be final

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1 effective immediately.

2 MR. PETERS: Thank you.

3 CHAIRMAN PALESTRO: Any other comments
4 or questions? Any comments from anyone on the
5 telephone lines? Dr. Tapp, I have a question for you
6 going back to one of your earlier slides on the
7 medical event evaluations. You said that you
8 presented your data at the Agency Action Review
9 Meeting of the Commission back in June. Is that
10 presentation available to the ACMUI?

11 DR. TAPP: It is a public presentation
12 and we can get it to you.

13 CHAIRMAN PALESTRO: Yes, I think it would
14 be particularly important for the Medical Events
15 Subcommittee to have the opportunity to look at it.

16 DR. TAPP: I will say it was a, the Agency
17 Action Review Meeting is a NRC-large meeting, so it
18 was one slide, I believe. But I can get that to you.
19 And there's a SECY paper associated with it with more
20 details, and we can provide that.

21 CHAIRMAN PALESTRO: Okay.

22 MR. BOLLOCK: This is Doug Bollock, NRC.
23 We can also provide you, we had a, prior to that we
24 had a Commission business line meeting that this
25 topic, the Agency Action Review Meeting, this one

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1 slide was kind of a synopsis of the larger
2 presentation to the Commission, and we can share that
3 with you.

4 CHAIRMAN PALESTRO: Okay, thank you.

5 MS. COCKERHAM: Dr. Palestro, could I ask
6 Dr. Tapp one more question? So there's going to be
7 a draft version of the guidance that comes out of,
8 this is a follow-up on Mike's question, draft
9 version's going to come out of OAS NRC Working Group.
10 It's going to go to the ACMUI in draft format. Will
11 that draft be publicly released?

12 DR. TAPP: We normally don't release the
13 draft that goes to the ACMUI.

14 MS. COCKERHAM: So then when the ACMUI
15 provides comments, how will the public know what their
16 comments are on what draft that they reviewed, to be
17 able to see what's going into the final?

18 DR. TAPP: They can provide comments on
19 the recommendations from the ACMUI, but they will not
20 be able to provide, the public will not likely see
21 the draft licensing guidance. We don't normally
22 release that as it's a pre-decisional licensing
23 guidance.

24 MS. COCKERHAM: But we will see the
25 ACMUI's comments?

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1 DR. TAPP: Yes, you will see the ACMUI's
2 recommendation and comments.

3 MS. COCKERHAM: Thank you.

4 CHAIRMAN PALESTRO: Any other comments
5 or questions? Dr. Tapp, just again, one quick
6 question. When would you expect that the guidance
7 will be ready for review?

8 DR. TAPP: We're hoping this winter.

9 CHAIRMAN PALESTRO: Okay, all right. So
10 then we will be forming a subcommittee to review it,
11 yes, okay. Considering Dr. Dilsizian and Mr. Ouhib's
12 enthusiasm for it, look forward to having you on the
13 subcommittee.

14 MS. HOLIDAY: Dr. Palestro, I'm sorry,
15 if I could just follow-up to the question that Ms.
16 Cockerham just asked and Dr. Tapp just answered. So
17 we recently engaged in some discussions with our
18 Office of General Counsel.

19 So actually, by the time that Dr. Tapp's
20 working group is getting ready to provide its draft
21 licensing guidance to the ACMUI, our process is at it
22 goes to the ACMUI for comment. It also goes to our
23 NRC regions and our agreement states for their comment
24 as well.

25 But because the ACMUI is going to provide

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1 its comments in the form of a subcommittee report in
2 a public ACMUI meeting, we have in our discussions
3 with Office of General Counsel agreed that going
4 forward we will also release that draft licensing
5 guidance, so that members of the public can see the
6 document that the Committee is commenting on.

7 But that is with the understanding that
8 if members of the public are providing comments, those
9 comments are on the ACMUI's subcommittee report. It
10 is not an opportunity for the public to submit
11 comments on the draft guidance itself. It's kind of
12 a weird do loop.

13 So when Dr. Tapp released her guidance
14 earlier this year in the Federal Register, I think it
15 was in the Federal Register, that was an opportunity
16 for members of the public to provide their comments
17 to staff. So then the next step from there is her
18 working group has looked at those comments and they're
19 in the process of developing or making further
20 revisions to their guidance.

21 So then it's that final bite at the apple
22 that goes to the ACMUI, our regions, and the
23 agreements states. The licensing guidance will be
24 posted when the ACMUI subcommittee report is posted,
25 so that members of the public or professional society

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1 stakeholders, when they want to submit comments for
2 the ACMUI meeting, they will be able to provide their
3 comments on the ACMUI subcommittee report. Thank
4 you.

5 CHAIRMAN PALESTRO: Okay, thank you, Dr.
6 O'Hara. Any other comments or questions? Thank you,
7 Dr. Tapp.

8 We're a little bit ahead of schedule at
9 this point. Question for you: Can we take care of
10 any sort of administrative work at the present time?
11 For example, identifying the spring meetings dates.
12 Is that possible, can we do that now?

13 MS. DIMMICK: Sure. Hold on. Okay,
14 we'll move forward, taking a look at our spring
15 meeting dates, and we'll try to -- this is actually
16 March, but we don't see the March header. So I'll
17 give Katie a moment to try to adjust. I think when
18 we did the doodle poll there were no dates in March
19 that were selected or provided an opportunity for to
20 have a meeting based on feedback from the doodle poll.

21 So let's go ahead and go on down to April.
22 And then April from the doodle poll, it was the 15th
23 and 16th were dates that 11 of the 13, there were,
24 checking with Sophie. Thirteen, eleven? Okay, so
25 there were 11 responses to the doodle poll that had

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1 available April 15 and 16. So those, at this point,
2 would look like the first choice for a meeting.

3 Keep in mind that we need to have a
4 Commission briefing as well, so we need to have an
5 alternate date as a backup because of -- so before we
6 select an alternate date, my prompter is reminding me
7 I should ask if the 15th and 16th is still an
8 available date for those who responded to the doodle
9 poll. And for anyone that did not, is the 15th and
10 16th available or not available, if you should know
11 now?

12 CHAIRMAN PALESTRO: So is there anyone
13 who cannot make the April 15-16 meeting? Presumably
14 everyone can make April 15-16, so that should be our
15 first choice.

16 MS. DIMMICK: That would be our first
17 choice. The second choice was April 4 or 5, and I
18 believe there was some limitations by some
19 subcommittee members. It was Dr. Metter is not
20 available and one of those days would be a half-day
21 for Dr. Ennis.

22 Does this date work for everybody else?
23 Would these days work for everyone else? Again, as
24 a backup if the 15th or 16th did not work for the
25 Commission for our spring meeting.

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1 CHAIRMAN PALESTRO: Is there anyone else
2 who can't make those days? Lisa, what about the
3 third and fourth, that didn't work either?

4 MS. DIMMICK: Sophie has the message up,
5 so I'll.

6 MS. HOLIDAY: Sorry, guys, this is a
7 little confusing, since I sent the doodle poll out.
8 So based on the responses that I got, Dr. Dilsizian
9 was not available on the third and Dr. Metter was not
10 available on the third or fourth as well.

11 Another alternative set of dates is April
12 8 and 9. I mean, either sets of these dates, there
13 wasn't a unanimous vote. So as the Chair's
14 prerogative, by default you would just select one or
15 two backup dates. And pending Commission response
16 we could go from there.

17 CHAIRMAN PALESTRO: I'm sorry, what did
18 you say about April 8 and 9? I didn't hear you.

19 MS. HOLIDAY: April 8 and 9 was another
20 date that was a possibility. Again, we didn't get
21 full, unanimous vote on that, so if that's another
22 date that the Committee would like to consider
23 perhaps.

24 CHAIRMAN PALESTRO: When you say you
25 didn't get a full, unanimous vote, does that mean

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1 that not everybody completed it, or there were some
2 people who couldn't make it?

3 MS. HOLIDAY: Out of the 11 responses I
4 received, both April 3 and 4 and April 8 and 9 did
5 not get 11 out of 11 yeses.

6 MEMBER DILSIZIAN: April 3 I can revisit
7 if I'm available. So I can make the fourth, I can
8 make arrangements for the third if it's, if it comes
9 to that.

10 CHAIRMAN PALESTRO: I'm sorry, you can
11 make the fourth?

12 MEMBER DILSIZIAN: The fourth I
13 definitely can, I just thought the third was out, but
14 I can rearrange my schedule.

15 CHAIRMAN PALESTRO: Yeah, I think the
16 third and fourth would be better than the fourth and
17 fifth of April.

18 MS. DIMMICK: So we could go with the
19 15th and 16th as the first choice, and the backup as
20 the third and fourth.

21 CHAIRMAN PALESTRO: And just to point out
22 and really to remind everybody on the Committee that
23 in the past it has happened on occasion that the
24 Commission has identified a date that doesn't
25 correspond to any of these, and the presenters have

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1 had to come in for an extra day. So that potentially
2 could happen as well.

3 MS. DIMMICK: That's correct.

4 CHAIRMAN PALESTRO: All right. So just
5 a comment and a suggestion to the members of the
6 Committee, and especially the new members. Do not
7 wait to make your reservations at Bethesda North, or
8 you will not get a room. I can tell you that when I
9 head out of here at lunchtime, that's the first thing
10 I'm going to do.

11 I learned the hard way my first meeting
12 when Ashley actually called me up and asked me if I
13 had made my reservations and I said no. And she said
14 you may be out of luck, and I was. I wound up staying
15 I think at the Hilton, which is two train stops down.
16 So I am being quite serious, you really should get
17 online.

18 And I can tell you that I always book
19 both the first and second choices, and once it's
20 finalized then cancel that second choice, okay. So
21 hopefully now that I've given you that advice I won't
22 be locked out of a reservation. Thank you. So that
23 concludes that.

24 We also had an item that we were going to
25 put in the open forum regarding a, I want to say an

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1 addendum, but a clarification on the Nursing Mothers
2 Guideline. And I know that Dr. Metter had worked on
3 that statement, along with Mr. Green. And can we
4 take care of that now as well?

5 MS. DIMMICK: Yes, we can.

6 CHAIRMAN PALESTRO: Okay, Dr. Metter.

7 VICE CHAIRMAN METTER: Yes, I defer to
8 Dr. Green.

9 MEMBER GREEN: So this is a draft of the
10 language that we might be putting on that that says,
11 This document was developed in September 2018 and
12 reflects the FDA approved radiopharmaceuticals on the
13 market at that time.

14 Licensees are obligated to carefully
15 evaluate radiopharmaceuticals that are not
16 encompassed in this document to keep exposures AL
17 ALARA to patients, staff, and members of the public.

18 CHAIRMAN PALESTRO: Comments?
19 Questions? Any comments from the attendees in the
20 room or on the phone? So I presume we need a motion
21 for this.

22 MS. DIMMICK: So is there a motion to add
23 the statements provided by Mr. Green to the Nursing
24 Mothers Guideline?

25 MEMBER OUHIB: This is Zoubir.

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1 CHAIRMAN PALESTRO: Second. Suh. Any
2 discussion? All in favor? Any opposed? Motion
3 passed.

4 MS. DIMMICK: Motion passed.

5 CHAIRMAN PALESTRO: All right, we will
6 resume at 10:45.

7 (Whereupon, the above-entitled matter
8 went off the record at 10:05 a.m. and resumed at
9 10:44)

10 CHAIRMAN PALESTRO: The next
11 presentation is entitled Compounding of -- excuse me
12 -- "Compounding of Sterile and Non-Sterile
13 Radiopharmaceuticals" and, Mr. Richard Green will
14 make the presentation.

15 Mr. Green?

16 MR. GREEN: Thank you, Dr. Palestro, I
17 appreciate the opportunity. I proposed this to be
18 added to the agenda.

19 I know talking offline with many of the
20 members of the Committee that some were aware and
21 some were not aware, and this is, I think, literally,
22 once in a lifetime paradigm change. So, I thought
23 it would be appropriate that we discuss this.

24 I've entitled this using the actual
25 formal title of the chapter and that is

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1 "Radiopharmaceutical Preparation, Compounding,
2 Dispensing and Repackaging," because each of those is
3 a different and distinct act. And, we're using
4 terminology from the FDA.

5 So, I'll start off by really discussing
6 -- next slide please -- who the United States
7 Pharmacopeia is. They're a private, nonprofit
8 standard setting body for pharmacy and medicine and
9 food as well.

10 They establish legally enforceable
11 national standards. I often use -- hear other people
12 use the wrong terminology, they're not guidelines,
13 they're not suggestions, they are standards.

14 And, these can be legally enforced when
15 recognized and incorporated into laws and
16 regulations.

17 Next slide, please?

18 So, the mission of the United States
19 Pharmacopeia is to promote public health and benefits
20 practitioners and patients by disseminating
21 authoritative standards and information developed by
22 its volunteers from medicines, other health care
23 technologies and related practices used to maintain
24 and improve health and promote optimal health care
25 delivery.

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1 Next slide, please?

2 So, USP, I guess the National Formulary
3 and the Pharmacopeia started back in the 1800s and
4 it's published every five years.

5 Chapters that are numbered above 1000 are
6 termed General Information chapters. They're good
7 advice, good guidance.

8 But, chapters numbered below 1000 are
9 official and can be enforced by the FDA or other
10 regulatory agencies.

11 Next slide, please?

12 So, the USP sets standards, other bodies
13 may enforce those standards. It could be the FDA
14 does the enforcement agency, they seldom visit
15 pharmacies or hospitals or clinics without cause.

16 If you have a sentential event, they may
17 knock on your door and ask you questions.

18 In my world, the Boards of Pharmacy are
19 the enforcement agents that come and visit us on an
20 annual basis to make sure we meet these standards.

21 CMS and their deemed accreditation bodies
22 are the folks at will be visiting hospitals and that
23 could be the HFPA, the American Osteopathic unit or
24 the most largest unit is the Joint Commission.

25 But, there's several deemed agencies that

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1 are going to come around and make sure that you're
2 meeting the standards established by CMS.

3 So, those will be the enforcement -- the
4 enforcers of the standards.

5 Next slide, please?

6 I wanted to point out that, although
7 we're talking and this title is Chapter 825,
8 radiopharmaceuticals today are currently under USP
9 standards which is Chapter 797.

10 I've rarely traveled without my well-worn
11 worked up copy. This lives on my desk and I have to
12 frequently review that for all the various State
13 Boards of Pharmacy that I am involved with.

14 So, since 2004, radiopharmaceuticals have
15 been subject to, I want to just read just a few
16 paragraphs.

17 The standards of this chapter are
18 intended to apply to all persons who prepare compound
19 and sterile preparations and in all places where CSPs
20 are prepared, hospitals and other healthcare
21 institutions, patient treatment clinics, pharmacies,
22 physicians' practice facilities and other locations
23 where CSPs are prepared, stored or transported.

24 Persons who perform sterile compounding
25 include pharmacists, nurses, pharmacy technicians and

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1 physicians, anyone.

2 Next slide, please?

3 Again, from the current 797 chapter,
4 these terms recognize that most sterile compounding
5 is performed by or under the supervision of
6 pharmacists and pharmacies, but also, that this
7 chapter applies to all healthcare personnel who
8 prepare, store and transport CSPs.

9 And then, they go on to state, that for
10 the purposes of this chapter, compounded sterile
11 preparations includes any of the following, and
12 you'll notice that radiopharmaceuticals are expressly
13 listed as being included under the standards of
14 Chapter 797.

15 So, we've been dealing with 797 for since
16 2004. And, Chapter 797 went out to revision and was
17 released in a draft revision in September 2015 and
18 there was public comment period on that revision until
19 2016 in January.

20 USP received more than 8000 comments from
21 over 2500 stakeholders. I personally wrote them a
22 65-page letter detailing line by line suggestions,
23 comments, grammatical changes and actually,
24 sometimes, even now, kudos a job well done. So,
25 comments were received.

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1 Today, in the chapter, there are six
2 small paragraphs related to radiopharmaceuticals.
3 But, the entire chapter applies to RPs.

4 So, we are lumped in with everybody else
5 and we have to meet the standards for a hospital
6 that's making an IV add mixture or compounding a drug
7 product that might have a 90-day beyond use date and
8 we have to wear booties, bouffants and beard covers
9 and, you know, get that garbed in a level of
10 cleanliness for, you know, we'd be happy with a 24-
11 hour BUD, a 24-hour use with our
12 radiopharmaceuticals.

13 So, we realize that we're currently in
14 the chapter, but there are many problems with 797 and
15 that's when we took the opportunity during this open
16 comment period to make comments.

17 Next slide, please?

18 As a result of those comments, the UPS
19 held a stakeholder workshop down the road in
20 Rockville, Maryland February 1st, 2017. I was in
21 attendance of that. I was an invitee and they invited
22 folks from the Sterile Compounding Committee that
23 writes 797 as well as members of the Nuclear Pharmacy
24 and Nuclear Medicine Community, SNMMI was present;
25 the FDA was present, USP staff.

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1 And, during that meeting, we expressed
2 the unique nature of radiopharmaceuticals, the short
3 BUD, the requirements for shielding, the use of remote
4 manipulators, all kinds of things that just made us
5 the square peg in a round hole.

6 And, we were successful in pointing out
7 the uniqueness of the radiopharmaceutical
8 preparations and they consented that
9 radiopharmaceuticals should have a separate chapter.

10 Next slide, please?

11 So, they put out the call for experts,
12 and that was done in June of 2017. They received
13 more than 60 applicants for the expert panel.

14 Next slide, please?

15 The -- here's the expert panel target
16 candidates characteristics, nuclear medicine
17 expertise in the commercial setting, a hospital
18 setting, an academic setting, experience with Boards
19 of Pharmacy, board certification in Nuclear Pharmacy,
20 members of the Expert Sterile Compounding Committee
21 that currently house those six small paragraphs on
22 radiopharmaceuticals.

23 And so, next slide, please?

24 I believe it was August of that year they
25 announced membership of the expert panel, and this is

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1 the membership today.

2 I've indicated who's on the Committee,
3 the expert -- sorry, the expert panel, who is a board
4 certified Nuclear Pharmacist, who's representative of
5 the FDA and who's on the expert committee for sterile
6 compounding.

7 I was honored to be selected to be on
8 this expert panel.

9 Next slide, please?

10 So, again, here's the breakdown, you can
11 see the Committee with its institutional members of
12 institutional nuclear medicine, commercial nuclear
13 pharmacy, academia, regulatory and consultants.

14 So, if we can take the next slide, we'll
15 transition into actually talking about this chapter,
16 825 has been identified the chapter it will be.

17 And, its scope is to provide clear and
18 effective USP public standards that meet patient and
19 practitioner needs for compounding sterile
20 radiopharmaceuticals today and in the future.

21 The proposed new General Chapter will
22 delineate compound activities for
23 radiopharmaceuticals and provide standards and
24 associated with these activities.

25 When complete, the General Chapter will

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1 contain standards for this class of products.

2 Next slide, please?

3 So, this charter in its draft form was
4 released for public comment on the internet on July
5 27, 2018.

6 Something else I -- I'm sorry -- I don't
7 travel without is the draft.

8 So, the public comment period is now open
9 and this draft chapter states that this chapter
10 applies to all practice settings where
11 radiopharmaceuticals are prepared, compounded,
12 dispensed or repackaged.

13 Practice settings consist of state
14 licensed nuclear pharmacies, federal nuclear pharmacy
15 facilities and other healthcare facilities including,
16 but not limited to nuclear medicine departments in
17 hospitals and clinics, nuclear cardiology clinics and
18 other specialty clinics.

19 Next slide, please?

20 This chapter applies to all individuals
21 who prepare, compound, dispense or repackage
22 radiopharmaceuticals. Applicable individuals
23 consist of authorized nuclear pharmacists and
24 authorized user physicians as well as individuals
25 working under their supervision.

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1 This includes, but is not limited to
2 student pharmacists, nuclear pharmacy technicians,
3 nuclear medicine technologists, students, physicians,
4 physician residents and trainees.

5 Next slide, please?

6 The purpose of 825 is to provide uniform
7 minimum standards for the preparation, compounding,
8 dispensing, repackaging of sterile and non-sterile
9 radiopharmaceuticals.

10 As a side note, there are separate
11 chapters today. There's Chapter 828, Chapter 795 for
12 non-sterile radiopharmaceuticals or non-sterile drugs
13 which iodine-131 would fit in that chapter and then
14 sterile is under 797 but we're proposing that all
15 RPs, sterile and non-sterile, go in this one chapter.
16 They are unique.

17 So, it will be sterile and non-sterile
18 radiopharmaceuticals for humans and animals that
19 occurs as part of state license activities.

20 And so, again, in the chapter, we define
21 the define the different terms of preparation,
22 compounding, dispensing and repackaging.

23 The chapter goes into the standards for
24 those activities, requirements for the environment,
25 for engineering controls whether they be in the room

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1 or the device, the laminar flow hood that is used to
2 prepare the drugs, the qualifications of personnel
3 involved in these activities and the practices are
4 necessary and balanced to ensure personal safety,
5 environmental safety and patient safety.

6 Next slide, please?

7 I've provided with the kind assistance of
8 Ms. Sophie Holiday, the table of contents from the
9 draft chapter. And, you can see it's very extensive.

10 It's a chapter that has two audiences.
11 One is the practitioner who will meet these standards.

12 And, the other audience is our
13 inspectors, whether that be a joint commission
14 inspector or a Board of Pharmacy inspector because
15 they don't really know what they're looking at. Now,
16 they'll be given an education. And, we talk about
17 time, distance and shielding.

18 We talk about ALARA. There's a reason
19 why I don't hold reactive syringes up against the
20 white background and then against a black background
21 to look for things. You do that in an IV bag, but
22 not in a radiopharmaceutical because of ALARA.

23 So, it goes into the qualifications, the
24 training, the hygiene.

25 Next slide, please?

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1 Facilities, which would include facility
2 design, environmental controls, microbiological air
3 and surface sampling, HEPA filtration of rooms, of
4 devices, cleaning and disinfecting of rooms, devices,
5 gloved fingertip sampling, gowning and garbing.

6 Next slide, please?

7 It gets into the term we use of beyond
8 use date; a manufacturer puts an expiration date on
9 their unopened drug product. But, once prepared and
10 handled in a particular clinical setting or a
11 pharmacy, then that term changes to what's called a
12 beyond use date that may certainly change different
13 from the manufacturer.

14 You may have a manufacturer's expiry of
15 five months from now, but once you make that drug,
16 depending on your setting and how you made it, you
17 will certainly have to reduce that beyond use date.

18 But, that's established here as to what
19 beyond use dates could be.

20 How to document. And then, we get into
21 the different activities of preparation where we're
22 making a commercially available drug product. All
23 of the kits, you know, Tech-99, MAA Kit for the
24 preparation of compound X versus compounding where
25 you are literally cooking from scratch, taking non-

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1 sterile ingredients and rendering them sterile, doing
2 a pyrogen test and making it suitable for human use.

3 Versus, on the next slide, please,
4 dispensing which is merely taking something that was
5 ready made like F-18 FDG that comes from a
6 manufacturer, dispense it and also repackaging,
7 similar process, so just changing the container
8 closure from the big glass bottle to a patient unit
9 dose syringe. That is dispensing and repackaging.

10 What quality control measures must be
11 taken as well as glossary and some example diagrams.

12 Next slide?

13 We can talk about the time line for
14 comments. So, it was released publically July 27th
15 and it will be open for comment. There will be a --
16 the USP will host an open microphone session to
17 discuss the chapter on October 10th.

18 And, the chapter has -- well, will be
19 published in the Pharmacopeia form in the
20 September/October edition. It was released early on
21 the internet to give the community more time to
22 respond and provide comments.

23 Next slide, please?

24 So, the time line for comments and when
25 it will become official. So, the comment period will

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1 end on November 30th, 2018, roughly two months from
2 now.

3 And, in the absence of any adverse
4 comments to the proposed chapter, it will become
5 official on December 1st, 2019.

6 That 2019 date is a magical date. There
7 are actually four chapters all becoming official on
8 that date. The 795 for non-sterile pharmaceutical
9 compounding, 797 for traditional sterile drug
10 compounding, 800 for hazardous drug or chemotherapy
11 drug compounding, both sterile and non-sterile.

12 And, radiopharmaceuticals in this Chapter
13 825.

14 So, they all will become effective on
15 that same day enforceable official on that same day.

16 Next slide, please?

17 So, this presentation is a heads-up to
18 members of the Committee as well as to staff at the
19 NRC that this is in progress. This is a once in a
20 lifetime opportunity to hopefully positively affect
21 the standards of care and the practice.

22 There may be some licensees that are
23 looking, once the draft gets revised and becomes
24 official in June of 2018, there may be an amendment
25 request to modify facilities or to put infrastructure

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1 in or to change procedures and processes.

2 So, it's a heads-up to staff.

3 So, our next slide provides resources.

4 The -- one of the great impetus behind this chapter
5 was a white paper that was made -- authored by SNMMI
6 and that's provided for your review.

7 And, also, I provided the link to where
8 you could download a draft copy of Chapter 825 if you
9 wish to read that yourself.

10 I encourage any member of the Committee,
11 or any member of the audience in the room today that
12 if you have concerns, positive comments, negative
13 comments, comments or suggestions for improvement to
14 take the opportunity to make public comment until
15 October -- until November 30th.

16 And, if you wish, you can attend the open
17 microphone session.

18 The next two slides are really acronyms
19 used in the presentation and that concludes.

20 CHAIRMAN PALESTRO: Thank you, Mr. Green.

21 Comments or questions from the Committee?

22 Ms. Shober?

23 MEMBER SHOBER: Yes, this is Megan
24 Shober.

25 Richard, could you speak to a little bit

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1 more about what some of the changes are that might
2 drive modifications to facilities or equipment?

3 MR. GREEN: There's a table, Table 7,
4 that addresses beyond use dates. And, let's start
5 with the lowest term is immediate use.

6 I could prepare a radiopharmaceutical on
7 the counter top ambient air, but it has to be used
8 within one hour because there's been no controls of
9 microbiological contamination.

10 If I'm going elute a generator, it needs
11 to be in a particular environment of known air
12 quality. And that would require, perhaps HEPA
13 filtration in the room.

14 If I'm going to prepare a drug inside a
15 laminar flow hood for beyond use date, you know, up
16 to 24 hours, well, that would require the installation
17 of a HEPA filtered laminar flow hood or a primary
18 engineering control.

19 That may be a change in infrastructure.
20 It won't change their radiological profile at the
21 facility, but it is going to be a change to the
22 facility.

23 There may be, in some places, depending
24 on the activities that they pursue, they may actually,
25 you know, change walls and divisions within the space.

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1 But, that's why we're giving a heads up to the NRC
2 staff.

3 CHAIRMAN PALESTRO: Any other comments?

4 Mr. Sheetz?

5 MEMBER SHEETZ: Thank you.

6 Very interesting and thorough
7 presentation, Mr. Green.

8 Two questions. One, will these standards
9 be applicable to radioactive drugs that are not FDA
10 approved?

11 MR. GREEN: Yes, they will. There's not
12 nearly -- FDA drugs, they could be research compounds,
13 clinical trial compounds.

14 For example, Chapter 823 is for positron
15 emission tomography drugs that you're probably
16 familiar with that are going through clinical trials.

17 There's FDA CGMP, or current good
18 manufacturing practice, standards for manufacturers
19 of positron emission tomography drugs. But, if you
20 are research chemist or a physician doing research in
21 PET drugs, then you need to apply 823.

22 So, yes, this applies to research
23 compounds as well.

24 MEMBER SHEETZ: Okay. But, the PET
25 radiopharmaceuticals or PET radioactive drugs will

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1 still be in 823?

2 MR. GREEN: Yes.

3 MEMBER SHEETZ: Okay. And then, the
4 other question I had is that these standards would be
5 applicable to animals? Would this apply to animals
6 used in research?

7 MR. GREEN: That's a good question, never
8 considered that. We do dispense radiopharmaceuticals
9 for non-research animals, horses, dogs, I've done an
10 elephant, it's a big bone scan.

11 (Laughter)

12 MR. GREEN: I don't know, that's a great
13 comment. I'd love to have you put that in the -- in
14 a comment.

15 MEMBER SHEETZ: Yes, because for research
16 to meet these standards would be difficult, it would
17 be challenging.

18 CHAIRMAN PALESTRO: Dr. Martin?

19 MEMBER MARTIN: Is there a plan to
20 present this typical scenarios in a question or like
21 frequently asked questions format?

22 I'm coming back to the earlier question
23 of so it's very obvious what the differences are
24 between say, standard practice today and what a
25 facility would need to change to implement, just like

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1 you said, I'm going to prepare this
2 radiopharmaceutical to use within one hour.

3 It would be very helpful to see these in
4 different type of scenario presentations and very
5 clearly spelled out so that, (a) you do not have
6 reviewers from outside commissions coming in and they
7 are not going to be at the technical level that
8 certainly you are.

9 So, some of these frequently scenarios
10 that you encounter could be laid out as to what the
11 differences are and how a facility will have to make
12 changes to comply with that, that would be very
13 helpful.

14 MR. GREEN: That's a great suggestion,
15 I'll take that comment back. And, I, again,
16 encourage you to make that comment in the formal
17 format.

18 I can point out that since 2004, we've
19 been subject to the current Chapter 797. And really
20 nothing is getting more severe.

21 We're able to loosen some of these
22 standards that are applicable in the standards of
23 practice today because we're not going for 90-day
24 expiry. We're just working with nuclides that, you
25 know, poof, they're gone in a day.

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1 So, hospitals are subject to these
2 standards today. Now, they may not have gotten the
3 attention from surveyors because they may be focusing
4 on pharmacy and being going to the cath lab or the
5 respiratory therapy department or the nuclear
6 medicine department, all places where drugs are used.

7 But, I can surmise that once there's a
8 separate chapter for just radiopharmaceuticals that
9 surveyors will give more attention and we might have
10 knocks on the door of the nuclear medicine department.

11 CHAIRMAN PALESTRO: Any other comments
12 or questions from the Committee?

13 MEMBER SCHLEIPMAN: Just a question for
14 clarification.

15 CHAIRMAN PALESTRO: Dr. Schleipman?

16 MEMBER SCHLEIPMAN: Richard, you
17 mentioned compounded PET drugs over main in Chapter
18 823, but I thought the whole purpose was to put all
19 radiopharmaceuticals in 800.

20 MR. GREEN: I can -- whoops, let me get
21 the right one.

22 I will read one small part with your
23 indulgence. This chapter shall not apply to
24 radiopharmaceuticals manufactured in FDA registered
25 manufacturing establishments according to 510 of the

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1 Food and Drug and Cosmetic Act.

2 Radiopharmaceuticals compounded in FDA
3 registered outsourcing establishments according to
4 503(b) of the FDA Cosmetic Act.

5 Aspects of positron emission tomography
6 PET drug preparation as defined in the PET Chapter
7 823 and administration to patients.

8 So, once the manufacturer makes the PET
9 drug and gives it to me to dispense, then this chapter
10 is applicable.

11 MEMBER SCHLEIPMAN: Okay.

12 MR. GREEN: They make it under the mantra
13 of hocus pocus of the FDA.

14 MEMBER SCHLEIPMAN: Okay, thank you.

15 CHAIRMAN PALESTRO: Any other comments
16 or questions from members of the Committee?

17 (No response)

18 CHAIRMAN PALESTRO: Comments or
19 questions from attendees here in the room?

20 Ms. Holiday?

21 MS. HOLIDAY: This is Sophie.

22 In my role in the Office of Enforcement,
23 I would just like to make a clarification or
24 additional statement.

25 Earlier in Mr. Green's presentation, you

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1 saw in the time line and he made several references
2 about the term enforceable.

3 I'd just like to remind everybody that,
4 for NRC licensees and Agreement State licensees, we
5 would not take enforcement action unless a licensee
6 has a commitment or a tie down on their license which
7 makes it a legally binding requirement that they --
8 if the license says we will commit to following USP
9 standard blah, blah, blah.

10 So, unless they actually have that on
11 their NRC license or their Agreement State materials
12 license, or at least I can only speak for NRC, we
13 would not pursue enforcement action. That would not
14 be considered a violation.

15 It may be a violation for other aspects
16 or organizations that they are affiliated with, but
17 for NRC materials licensee purposes, it would not be
18 an enforcement action unless they actually have a
19 commitment tie down on their license that they would
20 be following these standards.

21 Thank you.

22 CHAIRMAN PALESTRO: Thank you.

23 MR. GREEN: Yes, thank you, Sophie. That
24 is a good clarification that the term enforceable in
25 this context was meant to be enforceable by the Board

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1 of Pharmacy or your accreditation organization, not
2 NRC enforceable.

3 CHAIRMAN PALESTRO: Any comments from
4 anyone on the telephone lines?

5 (No response)

6 CHAIRMAN PALESTRO: Thank you for the
7 presentation, Mr. Green.

8 All right. Next, we are going to move
9 on to medical team highlights. It will be presented
10 by Ms. Lisa Dimmick.

11 MS. DIMMICK: So, I'd like to offer a few
12 highlights of the medical team's efforts since
13 basically last October. Well, there's a few earlier
14 references in the presentation as well.

15 Next slide?

16 The areas that I wanted to just touch
17 upon is work under our areas in Commission papers,
18 rulemaking activities, NRC Agreement State Working
19 Groups and also guidance documents.

20 Next slide?

21 So, 2018 has been a year and things
22 leading up to 2018 made it extremely busy, but we did
23 have three SECY papers that we sent to the Commission
24 in 2018.

25 They were all information papers but they

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1 were -- there was substantial work that went into
2 each of these papers.

3 In January, we issued or we sent the
4 Commission a paper on SECY-18-0015, "Staff Evaluation
5 of the U.S. Nuclear Regulatory Commission's Program
6 Regulating Patient Release After Radioisotope
7 Therapy," in January of 2018.

8 This paper was the result of Commission
9 directed work.

10 The second paper we developed was SECY-
11 18-0037, "Review of the Emerging Medical Technologies
12 Program." We sent that up in March of 2018.

13 And, this paper was the result of staff
14 initiated work to evaluate our emerging medical
15 technology program. And, I do have a few more slides
16 to talk about those efforts.

17 And then, the third paper, we're all
18 familiar with. We've heard about it a few times
19 yesterday. It's SECY-18-0084, "Staff Evaluation of
20 Training and Experience Requirements for
21 Administering Different Categories of
22 Radiopharmaceuticals in Response to SRM-M170817."
23 And, that was in August of 2018.

24 Next slide?

25 So, just to recap some of the efforts of

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1 these papers, so SECY-188-0015, again, this was the
2 patient release.

3 In this paper, we provide the Commission
4 with staff's evaluation of the program for regulating
5 patient release after radioisotope therapy.

6 It also presents the results from dose
7 modeling calculations, review of published literature
8 and extensive stakeholder outreach.

9 Staff had concluded that the current
10 patient release program is protective of public
11 health and safety and that rulemaking to change any
12 of the release criteria in the regulations was not
13 warranted at this time.

14 Next slide?

15 The paper -- the staff also determined
16 that a comprehensive update to guidance as well as
17 updates to the equations and methodologies described
18 in the guidance for calculating doses to members of
19 the public from patients release was warranted.

20 And then, last, updating the NRC guidance
21 with current scientific knowledge would lead to more
22 accurate estimates of public dose from released
23 patients resulting in better licensee decisions
24 regarding the timing, circumstances and risks
25 associated with the patient release following

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1 byproduct material administration.

2 So, that was in essence the conclusions
3 and recommendations staff had and regarding patient
4 release.

5 Next slide?

6 The second SECY paper I wanted to discuss
7 was the staff effort in SECY-18-0037 to provide the
8 Commission with our review of the emerging medical
9 technologies.

10 This paper also identified staff's past
11 efforts with regard to medical -- emerging medical
12 technologies, emerging medical technologies that we
13 might be currently reviewing and emerging
14 technologies that we see coming down the pike.

15 So, this was a great effort for the
16 medical team to self-reflect on how we evaluate
17 emerging medical technologies and also so that we can
18 start planning ahead what types of things we're going
19 to be seeing coming down the line and so for basically
20 for resourcing purposes.

21 So, if I could, just a couple of things
22 before -- you can go ahead and go to the next slide.

23 So, Part 35, Subpart K that's also 10 CFR
24 35.1000 describes the process to obtain a license, a
25 license amendment or for a new medical use byproduct

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1 material, irradiation from byproduct material which
2 is not addressed in other parts of Part 35.

3 So, if an emerging medical technology is
4 not specifically addressed in 10 CFR Part 35, Subparts
5 D through H, staff will form a joint NRC Agreement
6 State Working Group to develop licensing guidance
7 describing an acceptable approach for meeting NRC's
8 regulations.

9 Also, if the emerging medical technology
10 is specifically addressed in Parts 35, Subparts D
11 through H, the staff may provide additional
12 information to assist in licensing and inspection
13 based on the specific risks associated with the
14 technology.

15 So, a couple of examples of some past --
16 recent past reviews, we have many more in our past,
17 but it was the NorthStar Medical Radioisotopes
18 RadioGenix Molybdenum-99/Technetium-99m Generator
19 System. That guidance was issued in February 2018.

20 The Eckert and Ziegler GalliaPharm
21 Germanium/Gallium-68 Generator, Pharmacy Grade
22 Generator, that was actually Revision 2 that was
23 issued in July of 2017.

24 And then, in 2016, we did the Low Activity
25 Radioactive Seeds Used for Localization of Non-

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1 Palpable Lesions and Lymph Nodes October of 2016.

2 And then, we also have a Leksell Gamma
3 Knife and Leksell Perfexion Icon from May of 2016.

4 And then, Revision 9 of the Yttrium-90
5 Microsphere Brachytherapy Sources and Devices
6 TheraSphere and SIR-Spheres was February of 2016.

7 So, there are more that predate those
8 2016 dates, but that's just a few of those samples.

9 Now, next slide?

10 That's some past reviews. I wanted to
11 show an example of some past reviews that we actually
12 did not do 35.1000 guidance for, but we evaluated
13 them to determine if they needed additional guidance
14 or if they were, in fact, 35.1000 guidance or not.

15 And so, in examples here are Lutetium-177
16 dotatate. We had determined that that could be
17 licensed under 35.1000, I'm sorry, 35.300. And we
18 did that determination in June of 2018.

19 We also had, last October, evaluated the
20 Salutaris Manual Radionuclide Eye Applicator and
21 determined that this could be licensed -- would meet
22 the criteria under 35.400.

23 And then, one that was previous a few
24 years ago was the Radium-223 Dichloride. And we
25 determined in 2013 that that could be licensed under

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1 35.300.

2 So those are examples of past reviews.

3 Next slide?

4 So, we have a few reviews in process right
5 now. There are two cobalt-60 stereotactic
6 radiotherapy devices. One is the MASEP Infini for
7 treating brain tumors and lesions.

8 And then, the other one is GammaPod for
9 treating breast cancers.

10 So, that's -- so there's an active
11 working group working on both of those devices that
12 will result in two separate guidance documents for
13 these stereotactic radiosurgery units.

14 We've already earlier talked about the
15 Yttrium-90 Microsphere Brachytherapy working Group
16 that's working to update the licensing guidance to
17 issue Revision 10.

18 And then, the Leksell Gamma Knife
19 Perfexion and Leksell Gamma Knife Icon, that will be
20 Revision 1 and this is the document that addresses
21 the physical presence requirements.

22 Next slide?

23 So, that was current work. Those are
24 actively in process.

25 So, we have many things that we've

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1 identified in this SECY paper of coming down the pike.
2 But, these are three of the items that are very near
3 future and, near future, I mean before the end of the
4 year.

5 It's likely that we might look to
6 establishing a 35.1000 working group to determine if
7 we need guidance for any of these three items, one of
8 them being the Phosphorous-32 OncoSil microparticles
9 for advanced pancreatic cancer.

10 Thorium-227 antibody therapy for
11 treatment of lymph node, prostate and breast cancer.

12 And then, another one, Radium-224 as
13 Diffuse Alpha-emitters Radiation Therapy. That
14 acronym is DART and that's for the treatment of solid
15 tumors by alpha particles.

16 So, here is a few 35.1000 -- we'll
17 evaluate if they need 35.1000 guidance so there is -
18 - it's a potential they may not.

19 But, these are our current emerging
20 technologies that we are starting to evaluate the
21 licensing needs.

22 Next slide?

23 So, the last SECY paper I wanted to
24 mention, again, this one we already talked about was
25 the T&E SECY paper.

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1 And, in this paper, staff provided our
2 initial results, status and next steps related to the
3 NRC staff's evaluation of training and experience
4 requirements for administering different categories
5 of radiopharmaceuticals for which a written directive
6 is required in accordance with 10 CFR part 35 Medical
7 Use of Byproduct Material Subpart E, Unleaded
8 Byproduct Material Written Directive Required.

9 Next slide?

10 So, those were the Commission papers that
11 we sent in 2018.

12 I wanted to touch on too, the other area
13 the working group, I'm sorry, the medical team
14 supports are rulemaking initiatives.

15 So, two rulemakings that I wanted to
16 discuss are the 10 CFR Part 35 Final Rule for Medical
17 Use of Byproduct Material, the Medical Events
18 definition, training and experience and clarifying
19 amendments.

20 And then, another rulemaking, Naturally
21 Occurring and Accelerator Produced Radioactive
22 Materials that came in as a petition for rulemaking
23 PRM-30-66.

24 Next slide?

25 So, we've already talked briefly about we

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1 know that Part 35 Final Rule was published in -- on
2 July 16th, 2018. It was Final Rule and also
3 implementation guidance was issued and published in
4 the Federal Register.

5 For this rule, the medical team is
6 developing or has developed training that we will be
7 giving to the NRC staff, NRC licensees, the Agreement
8 States, master material licensees and their
9 permittees.

10 We're going to conduct between October of
11 2018, probably through March of 2019, webinar
12 training sessions. And, we're planning at least
13 eight more if necessary to roll out the new Part 35,
14 if you will.

15 So, January 14th, 2019 is when the rule
16 -- Final Rule becomes effective for NRC licensees and
17 master material licensee compliance.

18 Three years from that date is would be
19 the effective date for the Agreement States.

20 Next slide?

21 So, just to recap a couple of the major
22 revision. There are separate requirements now for
23 identifying and reporting medical events involving
24 permanent implant brachytherapy.

25 The new rule also added requirements to

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1 measure the Moly-Tech breakthrough after each
2 generator elution. The new rule adds reporting
3 requirements for failed technetium and rubidium
4 generators.

5 The rule grandfathered certain board
6 certified individuals from certain T&E requirements.

7 And, the new rule adds the Associate
8 Radiation Safety Officer that could be named on a
9 materials license.

10 And we -- the rule also adds the
11 Ophthalmic Physicist that could be named on a license.

12 Next slide?

13 I wanted to mention this rule. And this
14 was a petition for rulemaking. It's the Naturally
15 Occurring and Accelerator Produced Radioactive
16 Materials.

17 In April of 2017, we received a petition
18 from the Organization of Agreement States, or OAS, to
19 amend 10 CFR Part 30 Appendix B.

20 Appendix B of Part 30 is used for
21 calculating decommissioning funding requirements.
22 And, in Appendix B, the default possession thresholds
23 for unlisted radionuclides is felt to be too
24 restrictive.

25 In 2005, Congress had authorized the NRC

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1 to regulate discrete sources of naturally occurring
2 and accelerator produced radioactive material, or
3 NARM.

4 NRC did not update Appendix B at that
5 time to add these NARM radionuclides to the table.
6 And, as a result, regulators feel that they must apply
7 burdensome decommissioning funding obligations or
8 evaluate exemptions that hinder the introduction of
9 new technologies and adversely affect patient care.

10 So, the petitioners in this case asked
11 the NRC to amend Appendix B to add appropriate
12 nuclides and their corresponding activities as
13 determined by a rulemaking group.

14 Next slide?

15 So, NRC is taking action on this
16 petition. In August of 2017, the NRC noticed the
17 petition in the Federal Register and requested public
18 comment.

19 Twenty comment letters were received. No
20 one opposed the requested rulemaking.

21 And then, in April, staff did formulate
22 a recommendation and conducted a Petition Review
23 Board.

24 So, currently, staff is preparing the
25 recommendation and Federal Register Notice for

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1 Commission review and decision.

2 I included this rule because I wanted to
3 point out that we do have medical team staff who do
4 -- are supporting this rulemaking effort with our
5 rulemaking division.

6 So, that's another role of the medical
7 team are to support any sort of rules that touch in
8 the area that touch the medical areas.

9 Next slide?

10 So, just a few things on the NRC Agreement
11 State Working Groups.

12 Next slide?

13 So, we currently have several active NRC
14 Agreement State Working Groups. I kind of already
15 mentioned this, but we do have NRC Agreement State
16 Working Group working on the MASEP Infini GammaPod
17 stereotactic devices.

18 This could be a cue for ACMUI that, down
19 the road, maybe next summer, you may see these draft
20 guidance documents coming your way for review. So,
21 that's something that's coming down to ACMUI probably
22 next summer.

23 The -- it is a NRC Agreement State Working
24 Group working on the Yttrium-90 as well as the Leksell
25 Gamma Knife.

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1 And then, another one that we haven't
2 talked on and I'm going to give a little more
3 information in a moment, but that's the Regulatory
4 8.39 -- Regulatory Guide 8.39 Release of Patients
5 Administered Radioactive Material Working Group.

6 And then, continued efforts by the
7 NorthStar Working Group as well.

8 Next slide?

9 So, in addition to the guidance documents
10 that might be put forth by those Working groups, we
11 have some other guidance documents I wanted to note.

12 So, go ahead, next slide?

13 So, the first one is the Germanium-
14 68/Gallium-68 Generators. Currently, the current
15 guidance for this generator is specific for the Eckert
16 and Ziegler GalliaPharm Ge-68 Gallium-68 Generator.

17 And, NRC foresees that there will be
18 other generators coming down the pike and that we
19 need to provide guidance for other generators as well.

20 So, we modified -- the medical team
21 modified this existing guidance document to be a non-
22 specific manufacturer licensing guidance.

23 The modifications really included minimal
24 word changes to create more of a brand neutral
25 guidance so that we would not have to always create

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1 a new guidance document that was manufacturer
2 specific if the guidance could apply to all types of
3 Gallium-Germanium generators.

4 So, no changes were made in the revision
5 that staff -- in the revision staff took. No changes
6 were made in the commitments, the breakthrough
7 limits, radiation safety to follow for the operation
8 of this generator.

9 And so, where we are with this now, we
10 have issued a radiation control program letter --
11 radiation control program director letter to the
12 Agreement States asking for comment. And, this is
13 one we will be looking to ACMUI to review as well so
14 that will be another subcommittee that we'll be
15 looking ahead to.

16 And, I think we're going to talk about
17 that later today.

18 But, anyway, so this guidance is, again,
19 intended to be not specific to a manufacturer so that
20 we won't hold up people from using other generators
21 that might come down the pike.

22 Next slide?

23 The Volume 9 and Volume 13 of the NUREG-
24 1556 series documents, so these have been in process
25 and under revision for a while.

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1 But, one thing that we were able to do is
2 amend or add revisions to both of these documents
3 that comport with the Final Rule.

4 So, the working groups that were drafting
5 these revisions that have been -- because these have
6 been in process for a couple of years.

7 So, as the rule was becoming final
8 towards completion, the working groups were able to
9 begin incorporating or identifying what would need to
10 change with these guidance documents so that they
11 comport with the Final Rule.

12 So, when these documents are released,
13 hopefully, sometime in early 2019, but they're
14 currently in the concurrence process.

15 But, once these are finalized, they will
16 comport with the Final Rule. So, they'll be current
17 with the Final Rule which is nice so we don't have a
18 situation where these guidance documents got way
19 ahead of the rule and got published and then having
20 to issue an addendum to them to align with the Final
21 Rule.

22 So, but when they are issued, they will
23 comport with the Final Rule -- Part 35 Final Rule.

24 And, I think that's all I have for updates
25 for the medical team.

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1 CHAIRMAN PALESTRO: Thank you, Ms.
2 Dimmick.

3 Any comments or questions from the
4 Committee?

5 Mr. Sheetz?

6 MEMBER SHEETZ: I have a question.
7 Currently, the Part 1000 uses have a Compatibility
8 Level D with Agreement States. So, if a new medical
9 device comes out, say, DART, and an Agreement State
10 starts to do an evaluation, how is that coordinated
11 with the NRC with respect to deciding on what category
12 it should be licensed under?

13 Because, DART, I could see it licensed
14 under Part 1000. I could also see it under 35.400.

15 So, that's from how that's evaluated?

16 MS. DIMMICK: So, we have pretty good
17 communication with the Agreement States. So,
18 typically, when an Agreement State sees a new
19 technology, especially that might be coming for their
20 -- to license it, they'll contact us to discuss, are
21 you planning 35.1000 guidance or, you know, what and
22 to move forward.

23 So, once we start to see where they are
24 with ready to license something, that will help us to
25 know when we might need to start a 35.1000 guidance.

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1 While 35.1000 is not a compatibility
2 requirement for Agreement States, they can use it if
3 they end up tying their licensees to that licensing
4 guidance. And, that's often what they do because
5 they might look to see how NRC would license that
6 product.

7 MEMBER SHEETZ: But, are they obligated
8 to engage you in that working group discussion?

9 MS. DIMMICK: No.

10 MR. BOLLOCK: Yes, they can -- the States
11 can independently, if a new technology comes in, they
12 can independently license that for use in their State.

13 I don't know if you have anything else to
14 add, Megan?

15 MEMBER SHOBER: Yes, this Megan Shober.

16 From a practical standpoint, I don't
17 think there's any State out there that has enough
18 technical expertise to really come up with one of
19 these -- a complete guidance set with our in house
20 staff.

21 So, we really have to pool the resources
22 from across the country and from the NRC to come up
23 with a good workable product.

24 And, I think that States want that -- we
25 want to work together to do that.

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1 MS. DIMMICK: If I might add, that with
2 many of these technologies, the first sites or
3 licensees that are using them are the medical broad
4 scopes. And so, there's enough flexibilities within
5 the medical broad scopes that they are able to
6 evaluate how they would use these sources and devices
7 in their facilities under -- with their broad scope
8 program.

9 CHAIRMAN PALESTRO: Any other comments
10 or questions from the Committee?

11 (No response)

12 CHAIRMAN PALESTRO: Comments or
13 questions from attendees in the room?

14 Dr. Ennis, I'm sorry.

15 MEMBER ENNIS: So, if everyone kind of
16 collaborates and cooperates, why not make 1000
17 Compatibility C at least? It makes me anxious a
18 little bit to think that a State could go rogue.

19 You know, who knows? Some manufacturer
20 who's got deep pockets or connections might get a
21 State to go along with something that we would be
22 uncomfortable with.

23 MR. PETERS: Sorry, Mike Peters, ACR --
24 do you want to -- sorry.

25 MS. DIMMICK: I'm trying to think how

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1 best to maybe -- we'll just take the comment in that
2 sense.

3 I don't foresee that sort of thing.
4 States will have a process. They might be able --
5 they have some flexibility as to how they could
6 identify how some things could fit in another area of
7 the regulations or how their regulations are written,
8 they might have a way that they could incorporate
9 some of these.

10 Because many of these technologies are
11 similar to other of the categories, but there just
12 might be some exceptions.

13 So, they might issue the -- go ahead and
14 issue it under another category with some level of
15 exception. I mean, there's just different ways that
16 they could do it.

17 MR. BOLLOCK: Right. And, I could add
18 an example, the Germanium Gallium Generator, the
19 reason it's not licensed under 200 is because there's
20 not a breakthrough limit and 200 has specific
21 breakthrough limits for the Moly generators and
22 Rubidium generators. It doesn't have it for
23 Germanium Gallium.

24 So, a State, maybe in theory, I think a
25 State could, for that type generator, I'd be confident

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1 that Megan could approve that with -- as a licensed
2 reviewer with, you know, some basic information
3 received from the, you know, in coordination with the
4 FDA or the manufacturer to safely license that.

5 So, there are, you know, that's right
6 there a real world one where I think there is the
7 capability of a State to do it. That may be the
8 reason why 1000 is, I don't know the reason why it's
9 in the regulations as the rule is written. It was
10 determined that the category was.

11 But, that right there is just a real
12 world, I mean, a reasonable example of why that could
13 be or in a situation where it would make sense and be
14 safely licensed.

15 I don't know if that helps, but the
16 reality is just the way the rule is written and the
17 determination for the compatibility was determined to
18 be, I think, give the States flexibility to do things
19 like that.

20 CHAIRMAN PALESTRO: Mr. Peters, you --

21 MR. PETERS: Sure, so I guess this is
22 more a question about the ACMUI interface with the
23 NRC and Agreement State work groups that work on the
24 licensing guidances.

25 Historically, it seems like controversy

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1 comes when those work groups differ from ACMUI
2 recommendations, at least as far as the medical
3 community is concerned.

4 Is there a reason, a technical reason why
5 ACMUI can't be more involved with the licensing
6 guidance draft revisions and stuff in a preliminary
7 fashion before they're actually drafted so that we
8 can lessen the controversies that pop up like we saw
9 with the Y-90 draft Revision 10?

10 MR. BOLLOCK: Yes, I can respond to that,
11 I don't know if Megan wants to chime in or some ACMUI
12 members.

13 We have actually frequently engaged with
14 specific ACMUI members who have expertise with the
15 technology, knowledge of the technology or, you know,
16 have constituents in their fields that can help
17 provide that information.

18 I know we've reached out to Ms. Weil on
19 a number of occasions, you know, Mr. Green, a number
20 of others on the Committee for -- to help us in that
21 development.

22 Recognizing, like you said, with -- there
23 is Y-90. The working group has an idea of something,
24 I think it's the pathways, right, which should there
25 be manufacturer pathway. That can still happen even

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1 if -- even with understanding what the ACMUI feels
2 the States have.

3 The working groups, typically, we get a
4 number of representatives from the States. They have
5 their way of doing things. There's kind of the
6 precedence for, you know, AUs. The precedence is,
7 once the -- if you have an established modality, AUs
8 train other AUs. Right?

9 That's looking at everything else, that's
10 the precedence that could, you know --

11 There are other reasons besides that. We
12 do -- but we do, staff absolutely does reach out to
13 our ACMUI members to get that insights in the early
14 stages in development. And then, we'll bring that -
15 - our staff members will bring that to the work group.

16 MR. PETERS: That's comforting to know.
17 And, I wasn't trying to volunteer these poor people
18 for additional work or anything like that.

19 (Laughter)

20 MR. PETERS: But, certainly, we like to
21 see ACMUI recommendations be sort of the standard
22 that the work group develops their licensing guidance
23 draft revisions and stuff around.

24 MR. BOLLOCK: Yes, we -- I mean, we
25 definitely take very seriously and that's why we have

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1 the Committee to advise the NRC staff. They advise
2 the staff, they advise through the staff to the
3 Commission.

4 The Commission makes the final decisions
5 or with the licensing guidance staff, you know,
6 through a review and our general counsel review, we
7 make the final decision on the licensing guidance for
8 the specific licensing commissions.

9 However, we don't always align exactly
10 with ACMUI, but we are -- I think the number is
11 somewhere around 85 percent, we accept about 80
12 percent fully accept what the ACMUI recommends. And
13 somewhere in 10, 14 percent of at least partially
14 accept what the ACMUI recommends to staff.

15 So, it is very rare that we -- that staff
16 does not agree with the staff or the Commission
17 doesn't agree with the Committee.

18 CHAIRMAN PALESTRO: Mr. Sheetz?

19 MEMBER SHEETZ: I guess I would like to
20 go back to Dr. Ennis's stated concern, and the same
21 concern I have, although I would just ask the question
22 and was dancing around it.

23 But, I'll bring up again, are we
24 comfortable with the current working relationship
25 between the NRC and the Agreement States for new

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1 technologies coming out?

2 My feeling is, the NRC should be involved
3 right up front with all of these because they have
4 the technical expertise and resources and they also
5 have the resources of the ACMUI to evaluate these new
6 technologies.

7 So, I guess my concern is, as Dr. Ennis
8 was pointing out, maybe an Agreement State would just
9 want to go alone and do their own thing.

10 And, they really have no obligation to
11 engage the NRC and they could pick the category and
12 license that under whatever category they wanted.

13 Some little concern, but I'm new to this,
14 and so maybe that concern is not founded.

15 MR BOLLOCK: In my experience, and this
16 is just my experience, it's very rare that we -- that
17 the State wouldn't share information with us at some
18 point. Right?

19 Because a lot of these technologies,
20 they're going through FDA approvals. They're only
21 at broad scopes. Right?

22 And, we learn, and actually, in the SECY
23 paper that Lisa referenced in her presentation, we go
24 through all the different ways that we, the NRC, hear
25 about the new technologies.

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1 And, the States are one of the primary
2 ones, the FDA is another one. ACMUI members are
3 another resource and then the manufacturers.

4 They come, you know, some manufacturers
5 know to come to us if they're --

6 And so, we do, you know, we're open to
7 this. This is why one of the reasons we have the
8 Committee.

9 Understanding the, I guess, the fear that
10 there could be a licensee that goes to a State, it'd
11 be rare that we're not, like I said, it's very rare
12 that we're not aware of that.

13 MEMBER SHEETZ: Not so much that they
14 wouldn't engage you, but they may engage you too far
15 down the road which is one of the concerns from the
16 ACR.

17 MR. BOLLOCK: And, so, again, back to
18 yesterday's presentation or one of yesterday's
19 discussions about the IMPEP reviews. If a State was
20 -- I'm not going to -- I'm just going to -- if they
21 went rogue, for whatever reason, and they were doing
22 something that wasn't -- that was outside what their
23 program is supposed to be, IMPEP reviews are one of
24 the -- is kind of the balance.

25 And, all the States, and even our

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1 regional -- the NRC regions are under the IMPEP
2 program and get reviewed in how they license and how
3 they inspect and how they enforce among their
4 programs.

5 So, that's -- I mean, there are checks to
6 that if those type things were occurring.

7 But, you know, the States are -- they are
8 Agreement States, they license their products in the
9 States. Again, it's, you know, we have a good
10 relationship with them and, you know, we typically do
11 work as a team.

12 Every one of these working -- the reviews
13 that the ACMUI of our 35.1000 guidance has come from
14 a working group with rare, rare, rare exception.

15 If there is a minor tweak update to a
16 revision, we may not go to the States. For instance,
17 the Germanium Gallium Generator, we just made it brand
18 neutral.

19 We shared with the OAS, said, are you
20 okay if we just make it brand neutral? You'll get a
21 chance to look at it, which they are -- all the States
22 are.

23 But, in almost every other case, they
24 have representatives on our groups that develop the
25 guidance. And, again, the guidance is specific

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1 license conditions that we deem necessary for the
2 safe of those modalities.

3 CHAIRMAN PALESTRO: Ms. Holiday?

4 MS. HOLIDAY: Did Megan want to speak
5 before?

6 CHAIRMAN PALESTRO: Ms. Shober?

7 MEMBER SHOBER: The thing that I just
8 want to add about the -- any of these licensing
9 guidances are major efforts to research and pull
10 together.

11 And, quite frankly, NRC doesn't have the
12 staff to do that by themselves. So, you're talking
13 like, I don't know, what do you have, six people,
14 maybe?

15 MR. BOLLOCK: When we're fully staffed
16 we have six.

17 MEMBER SHOBER: Yes, when you're fully
18 staffed?

19 And so, by drawing from Agreement State
20 resources, there's 150 people that could jump in and
21 provide substantial help in doing that.

22 So, it really is a national effort to
23 come up with a product like this.

24 MR. BOLLOCK: Yes, and there's a lot of
25 thought. Right? We try to work as a -- as one

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1 national program.

2 You know, everyone working together to
3 have, you know, put our best foot forward.

4 And so, as Megan stated, you know, we
5 have medical team staff of six people for all these
6 reviews. So, we do rely on the Agreement States to
7 help us.

8 They also have, you know, they've got
9 licensed inspectors that are out there seeing this
10 review, this. They're very familiar with it.

11 We also use our regional staff. So, out
12 of the three regional offices, we'll use because we
13 have our NRC license reviewers and inspectors.

14 So, that's how we get the -- another way
15 we get the resources to do these technical reviews.

16 And, as I said earlier, we will consult
17 with our ACMUI members to also help us fill us, you
18 know, fill the gaps.

19 And then, we'll -- and we do reach out to
20 the manufacturers and get the technical information
21 needed.

22 CHAIRMAN PALESTRO: Ms. Holiday?

23 MS. HOLIDAY: So, I'm got to try to give
24 my comments with respect to everything I've heard
25 from the Committee, from Doug, from Lisa, as well as

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1 Mr. Peters from ACR.

2 So, because there are newer members on
3 the Committee, a couple of years ago, I gave a
4 presentation to the Committee related to how it is
5 that we go about licensing 35.1000 modalities.

6 And how we also obtain information about
7 these technologies.

8 And, as Doug alluded to, there are
9 various ways that we learn about these technologies.
10 It could be through our MOU with the FDA. It could
11 be that the manufacturer comes directly to NRC and
12 informs us that they're getting ready to, you know,
13 develop some new technology.

14 It could be through an Agreement State
15 where they have the sealed sourcing device
16 registration within their State or they have a
17 licensee that has reached out for them, or potential
18 licensee asking to add it to their license.

19 It could be through one of our NRC States
20 where, you know, they are coming to us telling us
21 that they would like to get a license for this
22 modality.

23 So, once we get that information, it
24 could prompt the development of a joint NRC Agreement
25 State Working Group. It could be that if it starts

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1 from an Agreement State, they could come to us and
2 maybe ask our opinion about if this is how they should
3 go about licensing.

4 Or, ultimately, they may come to us and
5 say, hey, we are not sure how we want to do this, can
6 we start an NRC Agreement State Working Group?

7 You may have heard or you have heard over
8 the years about the importance of a national materials
9 program.

10 And, what that essentially is, is our
11 relationship with our co-regulators in the Agreement
12 States.

13 NRC currently has 13 States and there are
14 37 Agreement States. Come October, There will be 38
15 Agreement States and 12 NRC States.

16 So, really it -- a lot of our licensees
17 or a lot of the materials licensees are in Agreement
18 State space.

19 That being said, 35.1000 licensing
20 guidance or 35.1000 period, is the Compatibility D.
21 That does mean that Agreement States do not have to
22 follow NRC's 35.1000 licensing guidance.

23 As Megan said, you know, often times,
24 Agreement States do not have those resources to
25 develop their own guidance or how they would like to

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1 approach a certain modality.

2 So, they do tend to lean on the concept
3 of an NRC Agreement State Working Group.

4 However, there have been times where
5 Agreement States do go ahead and issue their own
6 licensing guidance or pursue how they want to license
7 a particular modality ahead of the NRC's guidance or
8 the NRC Agreement State's product being developed.

9 That has happened. That happened at
10 least for the Germanium Gallium-68 Generator where I
11 believe it was the State of Virginia that licensed it
12 ahead of us.

13 I mean, there are places like that. So,
14 I won't say I feel like rogue is a very strong word,
15 but, as we all have discussed in these meetings, often
16 times, the problem that physicians have is that, if
17 you are licensed to practice in one State, that is an
18 Agreement State, for example, New Jersey and New York.

19 The requirements in New Jersey may be
20 different from New York. And, the reason for that
21 is that, you know, at NRC, we have granted these
22 agreements with these states, hence, Agreement
23 States.

24 And, we have given them certain
25 regulatory authority for their program. So, you

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1 know, while it would be very ideal if we could have
2 a very uniform set of how we approach regulations,
3 because we have granted these authorities, it's just
4 not realistic to expect that.

5 Although, by default, as you heard from
6 Megan, very commonly Agreement States will wait for
7 these licensing guidance to be developed and they
8 just piggyback off of ours or they tailor it to fit
9 their needs.

10 But, often times, 80-plus percent of the
11 times, it is essentially our licensing guidance that
12 Agreement States will use.

13 Hopefully, that addresses everybody's
14 comments.

15 And, also, before I forget, Mr. Peters
16 brought up the notion about how we should be proactive
17 in engaging the ACMUI and that ACMUI's
18 recommendations should be the standard.

19 But, I would also like to remind you guys
20 that at ACMUI, you are an independent advisory
21 committee. The working group, the NRC Agreement
22 State Working Group is an independent working group
23 in itself.

24 The working group, in their charters, it
25 has language in there built in that they can reach

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1 out to the ACMUI should they need information or
2 advice or recommendations.

3 We also have the ability to reach out to
4 manufacturers if we have questions. And we often
5 times have done that.

6 I know, for example, for my Perfexion
7 Icon Working Group, we reached out to Dr. Suh several
8 times because, again, the purpose of this Advisory
9 Committee is that we do not have that medical
10 expertise on staff. That is why you guys are here.
11 That is why you are important.

12 So, yes, we do reach out to the ACMUI.
13 But, just like anything, ACMUI's recommendations are
14 independent. You advise staff, but ultimately, we
15 make the decision. We consider everything that you
16 inform us.

17 And, as Doug said, I mean, compared to
18 all of the federal advisory committees across the
19 U.S. government, we accept a lot of the Committee's
20 recommendations.

21 Many FACA Committees, agencies only
22 accept or implement less than 50 percent of their
23 recommendations.

24 So, that is to let you know that we highly
25 value your input and your advice.

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1 Thank you.

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

4 Any other comments or questions from the
5 Committee?

6 (No response)

7 CHAIRMAN PALESTRO: Attendees in the
8 room?

9 (No response)

10 CHAIRMAN PALESTRO: Attendees on the
11 phone?

12 (No response)

13 CHAIRMAN PALESTRO: All right.

14 All right, the next topic and final topic
15 before lunch is the open forum.

16 Anyone have any issues they'd like to
17 have addressed?

18 (No response)

19 CHAIRMAN PALESTRO: Have just one comment
20 that I would appreciate it if, and not before the end
21 of the meeting, but certainly in the next week or so,
22 and you've done it in the past.

23 If staff would put together a list of all
24 of the members of the ACMUI with their contact
25 information as well as what category they represent.

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1 It would be very helpful for all of us if
2 we want to contact one another. But, particularly,
3 for the Chair, me, when I have to put together
4 subcommittees, I can look at the various areas of
5 expertise.

6 And, along that line, with respect to the
7 radiation oncologists, I know there are some
8 subdivisions, brachytherapy and I forget the other
9 one off the top of my head, but I'd like to see that
10 in the list.

11 Mr. Bollock?

12 MR. BOLLOCK: Yes, we can get that for
13 you.

14 CHAIRMAN PALESTRO: Thank you.

15 Not just for me, I'd like to have it
16 distributed, obviously, to everyone.

17 MR. BOLLOCK: Right, we can distribute
18 that to the ACMUI members.

19 CHAIRMAN PALESTRO: Anything else before
20 we adjourn for lunch?

21 MEMBER SHEETZ: Yes, I do.

22 Yesterday, Dr. Metter presented the final
23 subcommittee document on breast feeding guidelines
24 and recommendations.

25 And there was some discussion on where

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1 that could be referenced or published or so forth.
2 So, I wasn't sure, one thing I saw was maybe it could
3 be referenced in the new 8.39 regulatory guide or
4 somewhere.

5 MR. BOLLOCK: Right, that's -- so, I was
6 going to remind the Committee, and thank you, Mr.
7 Sheetz, for that.

8 There are, yes, there are two things from
9 the Nursing Mother's Guide. I think the Committee
10 accepted a report, but there was specific -- there
11 was some discussion of specific language to say this
12 is -- this report is -- or the isotopes or
13 radiopharmaceuticals listed in this are -- that this
14 -- or these numbers are only for those listed in this
15 guidance.

16 CHAIRMAN PALESTRO: Yes, we acted on that
17 before.

18 MEMBER SHEETZ: Yes, that was acted on
19 this morning.

20 MR. BOLLOCK: Oh, I must have been --
21 sorry.

22 CHAIRMAN PALESTRO: That's okay.

23 MR. BOLLOCK: Yes, and then second, the
24 second one was, if the Committee has a recommendation
25 for staff on what you would like staff to do with the

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1 Nursing Mother's Guidance, is that correct, Mr.
2 Sheetz?

3 MEMBER SHEETZ: Yes, I think it's
4 important that it is referenced somewhere or included
5 as an attachment. I just don't know what documents
6 practically that could be referenced or attached to
7 it at this point in time without waiting multiple
8 years.

9 MR. BOLLOCK: Right. So, we are working
10 on updating a draft for Reg Guide 839 which is the
11 regulatory guide for patient release.

12 So, that is -- that's one appropriate
13 place for it. And, staff feels we're working on that
14 draft. It's a consideration because that's something
15 that's open now and we're working on.

16 And, that would be one appropriate
17 guidance document to attach that to.

18 But, if the Committee has any
19 recommendations, again, at the very least, the report
20 is on our ACMUI public website so people who want to
21 use it as a resource can find it.

22 And then, we can, you know, we can either
23 make it its own Reg Guide or we can attach it as, I
24 think we would probably prefer, it's much easier to
25 have it as an attachment or an Appendix to the updated

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1 Reg Guide 8.39.

2 Saying that, the -- how the Reg Guide
3 process works, we -- staff will draft the Regulatory
4 Guide and I know Said Daibes leading effort with an
5 Agreement State Working Group, that Agreement State
6 and Regional Working Group.

7 That'll then go to our Office of Research
8 that just runs the process of regulatory guides. It
9 will go out for public comment. So, there will be a
10 60 day comment period.

11 And if -- and that -- so then, the Nursing
12 Mother's Guide would be included as a -- if it's
13 included in the Reg Guide, it would be open for public
14 comment.

15 So, just for your awareness.

16 CHAIRMAN PALESTRO: Any other comments
17 or questions?

18 DR. DAIBES: yes, Said Daibes.

19 With respect to the question that was
20 raised, we have a section in Reg Guide 8.39 that will
21 address your raised concerns. So, we'll have a
22 section on guidance and some extractions of the report
23 that will be referenced back to the report, yes.

24 MR. BOLLOCK: Yes, in your working
25 group's draft guidance.

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1 DR. DAIBES: Yes, so that was determined
2 by the working group. And, we're Working on it.

3 CHAIRMAN PALESTRO: All right, thank you.
4 Any other comments or questions?

5 (No response)

6 CHAIRMAN PALESTRO: All right, just
7 before we adjourn, two quick items.

8 Number one, when you are making your
9 reservations at the Marriot under Group Code, make
10 sure you use N-18 so that you get the NRC rate.

11 And, number two, if before we leave, take
12 a couple of extra minutes here, need to get a group
13 photo.

14 Thank you.

15 MR. BOLLOCK: Thank you.

16 And so, is that -- so, what Dr. Daibes
17 shared, does that satisfy the Committee? No --

18 CHAIRMAN PALESTRO: I'm sorry, I didn't
19 mean to --

20 MR. BOLLOCK: -- for the Reg Guide, for
21 the Nursing Mother's Guidance, the work group's
22 decided that they believe it should be part of the
23 Reg Guide 8.39. Is that satisfactory to the
24 Committee?

25 MEMBER SHEETZ: Would you like a motion

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1 from the Committee?

2 MR. BOLLOCK: We don't need to do that.
3 That's the action we're going for.

4 MEMBER SHEETZ: That's great.

5 CHAIRMAN PALESTRO: Thank you.

6 (Whereupon, the above-entitled matter
7 went off the record at 11:57 p.m. and resumed 1:05
8 p.m.)

9 CHAIRMAN PALESTRO: All right. We're
10 going to reconvene now. Next topic on the agenda is
11 ACMUI Subcommittees, NRC Staff, NRC Management, How
12 the Team works under FACA.

13 And Mr. Chazell and Mr. Bollock will
14 discuss and present this.

15 MR. CHAZELL: Okay. Am I working? All
16 right. Hi everybody. My name is Russell Chazell.
17 I'm happy to be with you today. Thanks for the
18 invitation.

19 I work in the Office of the Secretary.
20 And I serve as the NRC's Federal Advisory Committee
21 Act, FACA, Committee Management Officer.

22 My role as CMO is to monitor the
23 activities of the NRC's three advisory committees.
24 The ACMUI of course, the Advisory Committee on Reactor
25 Safeguards, and the Licensing Support Network

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1 Advisory Review Panel.

2 So, those are the only three FACA
3 committees that the NRC has. There are other
4 agencies that have a lot more.

5 My job is to ensure that the three
6 committees comply with the requirements of FACA. And
7 Doug Bollock, who you all know, serves as the
8 Designated Federal Officer for ACMUI. And as the
9 DFO, he ensures that ACMUI complies with FACA.

10 So today I'll provide an agency level
11 overview of FACA. As well as discuss some ACMUI
12 history. And Doug will address some specific topics
13 later.

14 And I apologize if you've all heard this
15 stuff before. Hopefully you haven't. Hopefully it's
16 new to some of you. But, I guess we'll find out.

17 So, Congress when they passed FACA back
18 in the '70s, I think it was, intended for FACA
19 committees to do three things. Provide advice that
20 is relevant, objective, and open to the public.

21 Act promptly to complete their work. And
22 comply with reasonable cost controls and record
23 keeping requirements.

24 Further, the committees operating within
25 the confines of FACA, serve the public interest when

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1 they provide federal officials and the nation with
2 expert information and advice on a broad range of
3 issues affecting federal policies and programs. And
4 they participate actively in the federal government's
5 decision making process.

6 So, as you know from your own selection
7 processes, the NRC goes to great effort to ensure
8 that committee members can provide the kind of expert
9 advice sought under the auspices of FACA.

10 And because taxpayer resources are being
11 expended, FACA committees must comply with not only
12 FACA, but other federal laws such as the Government
13 and the Sunshine Act. And I've got the citations
14 there if you need a little -- if you're having
15 insomnia and you need something to put you to sleep.

16 There's Public Law 92-463 is FACA. And
17 Public Law 94-409 is the Government and the Sunshine
18 Act. And if you Google those, they'll come right up.

19 Additionally, FACA committees must comply
20 with regulations promulgated by the General Services
21 Administration, because they're the government-wide
22 program manager for FACA, and then the NRC.

23 So, implementing rules for GSA are 41 CFR
24 Parts 101-6 and 102-3. And those are the rules that
25 lay out details like you have to announce your

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1 meetings 15 calendar days in advance. And they have
2 to be published in the Federal Register and all that
3 kind of stuff.

4 And then the NRC's FACA implementing
5 regulations can be found in 10 CFR Part 7. Which is
6 in these books here.

7 So, in order to comply with FACA, each
8 committee must have a Designated Federal Official,
9 which in our case is Doug Bollock, pursuant to 10 CFR
10 7.11. And the DFR will -- the DFO will approve
11 meeting agendas, convene the meetings, attend the
12 meetings, adjourn the meetings, chair the meetings
13 when directed to do so, and ensure compliance with
14 laws and regulations.

15 So, next slide. This going to go really
16 quick. So here's a little history on ACMUI.

17 It was established on July 1, 1958. And
18 the Charter renews every two years. And one of my
19 jobs as CMO is to process the Charter renewals through
20 GSA.

21 And we sent up a SECY paper to the
22 Commission saying we want to go two more years with
23 this Committee. Do you approve?

24 And then once they do that and we consult
25 with GSA, then we file the Committee with GSA. And

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1 send copies of the Charter to the House of
2 Representatives, and the Senate, and the Library of
3 Congress.

4 ACMUI reports to the Division of Material
5 Safety Security State and Tribal Programs in the
6 Office of Nuclear Material Safety and Safeguards.
7 And my understanding is that the current MSST Director
8 is Daniel Collins. And the Deputy Director is
9 Sabrina Attack. So I presume you guys have already
10 met them, so.

11 There are 13 Committee members appointed.
12 You're all special government employees, which is a
13 special type of employee in the federal government
14 that limits your work effort to 130 days in any 365-
15 day period. And your pay is capped at the daily rate
16 for Level Four of the SES Schedule.

17 One of the requirements that we have from
18 FACA and the GSA implementing regulation is that we
19 provide them with a membership balance plan. And so
20 have to go through every two years when we renew the
21 Charter, and we just did that -- did this earlier
22 this year.

23 We have to provide a copy of that
24 membership balance plan to GSA. And it gets posted
25 on the GSA's database. Another thing you can look

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1 at if you have time, at FACAdatabase.gov.

2 And it has information on every FACA
3 committee in the government. And there's like 12 or
4 15 hundred of them. There's a lot of them.

5 And you can search by agency and see the
6 different committees. And you can see the reports.
7 And you can see who the members are. So you're all
8 listed on that database.

9 And that -- get whatever information you
10 might be interested in. And all kinds of different
11 committees.

12 But, for our purposes, the membership
13 balance plan for ACMUI includes healthcare
14 professionals of diverse specialties who represent
15 diagnostic and therapeutic applications of medicine,
16 medical administration, and patient care advocacy.

17 And that's what's in the Charter. And
18 so whenever we have vacancies, that's the template
19 that we have to follow when we solicit for new
20 members.

21 The terms are set at four years with a
22 limit of two terms. Members are appointed by the
23 Director of NMSS after consultation with the
24 Commission.

25 And as you know, I think I saw on your

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1 agenda that you had some ethics training yesterday.
2 All members must comply with federal ethics laws and
3 conflict of interest laws similar to what regular
4 government employees have to do. Although I know
5 there are some differences given the fact that this
6 is not your full time job, so.

7 Subcommittees. According to the Charter
8 there are no standing subcommittees for ACMUI. So,
9 any subcommittee work you do, my understanding is
10 that it's on an ad hoc basis.

11 One of the FACA rules is that
12 subcommittees must report to the full committee. So
13 the subcommittees don't necessarily provide their
14 output or their deliverables to the decision maker.

15 They have to provide it to the full
16 committee, which then would provide whatever they --
17 whatever output they wanted to the decision maker.

18 Meetings must be open to the public.
19 There are some narrow Government and the Sunshine Act
20 exceptions like personnel matters or internal process
21 things. But for the most part any substantive
22 discussions that you all have, have to be open to the
23 public.

24 And then as I said earlier, I'm the
25 Committee Management Officer, and I have to validate

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1 an annual report to the General Service
2 Administration. That then goes up to Congress so
3 that they can see, you know, what the taxpayers are
4 paying for.

5 And they do this on a government-wide
6 basis. And we provide input on our three committees
7 every year. And we upload it to this database.

8 And we have to consult with GSA to make
9 sure that the information that we are providing is
10 responsive to what they're looking for. And mostly
11 that information is how much did we spend?

12 How many government employees, regular
13 government employee FTE did we expend? So, we're
14 looking at money. We're looking at FTE.

15 We're also looking at if you -- if the
16 committee had contractor support of any kind, you
17 know, that information we'd have to put in there as
18 well.

19 We also have to make a recommendation as
20 to whether or not the committee is planning to
21 continue in the next fiscal year. You know, all
22 those kinds of resources, information that, you know,
23 decision makers in Congress when they're deciding how
24 much money they're going to spend, they want to know
25 that the money they are spending is being expended in

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1 a reasonable way.

2 And so that's about all I've got. Again,
3 it's been my pleasure to meet with you all. And I
4 can take any questions that you might have.

5 CHAIRMAN PALESTRO: Any questions or
6 comments from the Committee for Mr. Chazell?

7 (No response)

8 MR. BOLLOCK: Well then if the Committee
9 doesn't have any questions for Russ, I can -- there's
10 a couple of topics, some of them touch on FACA, some
11 of them are just normal ACMUI process that I know Dr.
12 Metter and Dr. Palestro can answer with no problem.

13 MR. CHAZELL: I can get out of your chair
14 here Doug. Thanks again for your time.

15 MR. BOLLOCK: No, it's working now. Last
16 chance to ask Russ a question before he leaves.

17 (No response)

18 MR. BOLLOCK: All right. So some of the
19 questions or some things -- questions that have come
20 up recently dealing with ACMUI subcommittees.

21 What is a -- and as Russ just said,
22 subcommittees, there's no standing subcommittees.
23 We've -- you've heard that from us before.

24 And their meetings are ad hoc. The
25 meetings are -- but any full committee meetings have

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1 to get on the public settings.

2 So, one of the questions is on
3 subcommittee size and composition. The reason for
4 the size restriction, that is a -- that is a FACA
5 compliance concern.

6 If a subcommittee is greater than -- if
7 you have 50 percent or greater of the full committee
8 meeting and deliberating, then it has to be done in
9 a public setting. So that's why we keep the
10 subcommittees at a -- when we have a full committee
11 of 13, the subcommittees can be up to six members.

12 So right now with a full committee, we
13 can have six members. Yes?

14 VICE CHAIRMAN METTER: So if you have an
15 open seat for our committee, does that make it less?

16 MR. BOLLOCK: Yes. And that has happened
17 about a year or two ago. I know we had -- I think
18 we were down to 11 or 10. So we had to get
19 subcommittees down to five or -- I don't know if we
20 ever had to go to four.

21 But I know we had to cut that.

22 VICE CHAIRMAN METTER: So my question is,
23 so let's say right now we have a full committee. And
24 let's say there are a couple of our members are not
25 -- the position is not filled.

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1 What about our subcommittee? Let's say
2 if we have to have a meeting on the -- before?

3 MR. BOLLOCK: Yeah. If it gets to the
4 point where members rotate off and there's a
5 subcommittee formed and they're working on something
6 and they're at six, and we have -- then the DFO or
7 one of the alternates would have to count, would make
8 a determination that we have to cut the subcommittee
9 down.

10 We would inform -- inform you. And we'd
11 have to remove a member from the subcommittee. So
12 that is a possibility.

13 VICE CHAIRMAN METTER: Okay. Thank you.

14 CHAIRMAN PALESTRO: Okay, before we go
15 on, I just want to clarify that. It was my
16 understanding, correct me if I'm wrong, that for
17 example we have 13 members, full committee. We have
18 six members on the subcommittee.

19 If two individuals who are not on the
20 subcommittee rotate off, we're not required to remove
21 someone from the subcommittee, are we?

22 MR. BOLLOCK: No, we are. Because that's
23 -- because then that would be greater than 50 percent
24 of the new full comm -- the full committee.

25 CHAIRMAN PALESTRO: I didn't think we had

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1 to. This came up before. I just want to double
2 check. I want to be clear about that.

3 MR. BOLLOCK: Sophie, you can correct me
4 if I'm wrong. But they will --

5 MS. HOLIDAY: Okay. So generally
6 speaking what Doug is saying is correct.

7 I think what you may specifically be
8 thinking of, because very rarely do we actually have
9 a subcommittee that has more than five individuals,
10 but Dr. Ron Ennis' subcommittee that reports out every
11 year on the medical events. You know, that -- we've
12 had discussions with the subcommittee.

13 You heard during Russ' presentation that
14 we don't have standing subcommittees. So while his
15 subcommittee reports every year, it's titled a
16 subcommittee.

17 It's not necessarily a subcommittee in
18 terms of pushing forward an action or a
19 recommendation. That subcommittee was pushing out
20 information, a review of the annual reported fiscally
21 -- fiscal year reported medical events.

22 So, for example, for that particular
23 subcommittee that had six members, we didn't have to
24 reduce the subcommittee membership for that. Other
25 subcommittees, for instance, Yttrium-90 or comments

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1 on other licensing guidance, training and experience,
2 those we would have, and are expected to reduce the
3 number of subcommittee members.

4 Because the idea is that when you are
5 presenting the subcommittee's report to the full
6 committee, because it has to be a product of the full
7 committee, the full committee takes a vote.

8 If you have six members on that
9 subcommittee, and say you only have ten members on
10 the committee, and six members on that subcommittee
11 are approving a certain motion, we support this. And
12 you only have four remaining members on the committee
13 that say we're against this, well by default the
14 subcommittee is the majority. So the motion would
15 carry.

16 So that's the reason why we have
17 membership less than 50 percent of the current number
18 of members on the committee.

19 MR. BOLLOCK: Right. And so it's -- and
20 Sophie, thanks for bringing up Dr. Ennis'
21 subcommittee. Because that -- that's normally what
22 they do by practice.

23 But yesterday I think you were -- you had
24 other things going. Yeah. They actually gave a
25 recommendation because they did a review and gave a

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1 recommendation to staff to do an information notice
2 based on an analysis -- a three and a half year
3 analysis. And not just going over the events and
4 sharing information.

5 So that would be --

6 VICE CHAIRMAN METTER: Can you explain
7 how that might be involved?

8 MR. BOLLOCK: So, if a subcommittee has
9 -- if the subcommittee is doing work coll -- well Sop
10 -- some of the examples Sophie was giving was the,
11 you know, the subcommittee had six members and even
12 with the changing. What the subcommittee did was
13 sharing information.

14 But when a subcommittee is deliberating
15 and the full committee -- for something the full
16 committee to vote on and then give action to advise
17 the NRC, you have follow -- right, you have to follow
18 the under 50 percent requirements.

19 MS. HOLIDAY: Well, I wasn't here for
20 that presentation.

21 MR. BOLLOCK: Right.

22 MS. HOLIDAY: But was there an actual
23 product that came out of Dr. Ennis' subcommittee? Or
24 was it after the subcommittee's presentation a
25 recommendation or a motion was put forth by the

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1 committee?

2 MR. BOLLOCK: They recommended that we
3 do an information notice giving examples of -- or
4 what they were -- yeah, what they thought were the,
5 I guess, best practices that could help prevent
6 events.

7 MS. DIMMICK: So, just to clarify, a
8 motion wasn't actually made to do that. That was a
9 recommendation the committee had. But we don't have
10 a motion on the record to make -- to do the
11 information notice.

12 There wasn't a motion made for the staff
13 to develop an information notice to move forward the
14 subcommittee's recommendations for the time out
15 procedure or other best practices.

16 So we didn't actually have a motion for
17 that yesterday. Just it was -- it will be reflected
18 -- or it's going to be seen unless we do that before
19 we convene today, it's just a recommendation that the
20 committee would have that it made in the meeting.

21 It's not a formal recommendation.

22 MR. BOLLOCK: Right. So, because of --
23 we have to be careful with what -- with what we do to
24 not violate FACA requirements, right. With what the
25 subcommittee's work does.

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1 And that's why generally we should -- or
2 general practice with a rare exception if they're not
3 going to have some sort of recommendation, would be
4 less than -- no more than 50 percent of the members
5 can be on the subcommittee.

6 CHAIRMAN PALESTRO: Any other comments
7 or questions on that Dr. Metter?

8 VICE CHAIRMAN METTER: I'm sorry. But
9 I'm still confused. So let's use Sophie's scenario.
10 Let's say the radiation oncologist and the
11 administrator positions do not get filled.

12 But let's say a committee of six
13 presented their final report. Then could -- that
14 means that the ACMUI could not vote on it?

15 MR. BOLLOCK: We would have -- no. We
16 would have to take a member off the subcommittee.

17 VICE CHAIRMAN METTER: So you would take
18 that person off the subcommittee. Okay.

19 MR. BOLLOCK: Right.

20 VICE CHAIRMAN METTER: That doesn't make
21 -- because that position would probably be the same.
22 I'm just --

23 MR. BOLLOCK: Well, if -- okay, if you're
24 talking time frames, the subcommittee did all the
25 work yesterday. And then today two members drop off.

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1 The work was already done. Following
2 FACA and everything is fine. Right? There's no
3 issues.

4 VICE CHAIRMAN METTER: But then who can
5 -- let's say --

6 MR. BOLLOCK: But going forward, if they
7 say there's further actions of that subcommittee,
8 that subcommittee would -- and going forward now that
9 the membership of the full committee dropped, they
10 would --

11 VICE CHAIRMAN METTER: Um-hum. Right.

12 MR. BOLLOCK: And we have done, I know
13 we have done this where we would have at least one
14 member of that subcommittee if they were going to do
15 further work, would then have to.

16 VICE CHAIRMAN METTER: But the -- let's
17 say the subcommittee presented their report, then
18 let's say a member has to then drop off. But then
19 it will still go to the full committee with a person
20 maybe being on a biased side.

21 I'm just wondering how the logistics --
22 you know what I mean on that. So, I'm just wondering
23 what would happen there.

24 Thank you Sophie for the explanation.

25 MR. BOLLOCK: Yeah. A lot of the reason

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1 it's for -- as Sophie said and the rules, or like
2 Russ had presented under the Sunshine Act, which is
3 the deliberations of what the federal government is
4 considering, is done in the public setting.

5 All right, so that's the main reason why
6 the membership has to be less. It's multiple
7 reasons. Like Sophie said, was the reason of you
8 could have that on -- that bias.

9 But it's also if you have -- we can't --
10 if you have deliberation of greater than 50 percent
11 of the committee, that has to be done in a public
12 setting. Because that is considered now enough for
13 a quorum of the committee.

14 And it has to be done in a -- under the
15 Sunshine Act has to be done in a public setting.

16 VICE CHAIRMAN METTER: Okay.

17 CHAIRMAN PALESTRO: You know, in
18 listening to this I think it can potentially become
19 a slippery slope with some of these committees,
20 subcommittees trying to figure out in some cases
21 what's simply reporting and where action is or maybe
22 required.

23 So, I think the -- I think the simplest
24 way to approach it is to ensure that when we're
25 forming the subcommittees, that there's always well

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1 under 50 percent.

2 So if we have a 13-member committee, if
3 we have a five-member subcommittee, probably very
4 unlikely that we're going to have to reduce that
5 number.

6 MR. BOLLOCK: Right. And you know, there
7 will be -- understanding there will be times when you
8 will want a sixth member.

9 And if after that members drop off and
10 you have to drop back down to five, the DFO will
11 inform you. And that will be done.

12 So there -- but yeah, I mean, that's a -
13 - that could be a practice that the committee decides
14 in forming subcommittees. You don't have to.

15 But again, it can run into that tricky
16 issue where there are members -- the full committee
17 drops in membership. And then the subcommittee would
18 then have to change its numbers.

19 CHAIRMAN PALESTRO: Thank you. I'm
20 sorry, Mr. Ouhib?

21 MEMBER OUHIB: Yeah. I think that might
22 be part of the -- what the responsibility of the chair
23 of that particular committee or subcommittee or
24 whatever, to prior to presenting anything if there's
25 any action item or something, perhaps to evaluate

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1 where are we on the count?

2 And should we propose that action,
3 because it might not qualify?

4 MR. BOLLOCK: We're still looking at,
5 it's the DF -- it's my responsibility to keep track
6 of that. Yeah. And so it's not -- it's not the
7 subcommittee's responsibility to keep track of that.

8 I mean, like in your practice, right?
9 You're all team players. You work in team
10 environments. You back each other up.

11 So, any, you know, if you recognize it
12 and bring it up, that's much appreciated. But that
13 ultimate responsibility does fall on the Designated
14 Federal Officer.

15 MS. HOLIDAY: Doug, if I can clarify
16 something. You stated that -- can you guys hear me?
17 Okay.

18 In the FACA rule which Russ gave a
19 citation to in his slides, the rule -- the final rule
20 that was published in 2001. It's actually silent on
21 the number of members that can be on a subcommittee
22 or a percentage.

23 This is more so an agency practice,
24 because we want there to be, I don't know if the work
25 is impartiality, or -- but we want to make sure that

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1 there's fair representation in terms of if there's
2 five members on a subcommittee that whatever motion
3 passes from the subcommittee that when it comes to
4 the full committee for a vote that it's not, you know,
5 like majority passes.

6 So, that is not a FACA requirement. That
7 is an agency best practice that we are applying to
8 this FACA committee.

9 As Doug said, it is the DFO's
10 responsibility. The chair keeps in mind, but it is
11 our job to make sure that we keep under that number.
12 Because that is our agency's best practice. And
13 should be the best practice for the subcommittee.

14 MR. BOLLOCK: Right. And so another --
15 just what a subcommittee of -- we have 13 members on
16 the committee, a subcommittee made of five members.

17 Public -- we have a public teleconference
18 on that subcommittee's report that five have been
19 voted on. We have nine members that are able to
20 participate.

21 We have a quorum that is considered a
22 quorum for the full committee to give a vote on. We
23 try to avoid that for the reasons that Sophie just
24 spoke on.

25 But that can happen. And we would be

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1 well within the FACA regulations.

2 CHAIRMAN PALESTRO: Any other comments
3 or questions before we proceed?

4 (No response)

5 CHAIRMAN PALESTRO: Okay.

6 MR. BOLLOCK: So, one of the other
7 questions that comes to us, in the make up and work
8 distribution and the NRC staff resource for
9 subcommittees.

10 So this is something, the staff resource,
11 I can speak to the NRC resource. We will provide a
12 resource to subcommittees to help provide
13 information, give clarifying questions, guidance as
14 far as just how our regulations work and what we are
15 doing.

16 The staff resource is not a member of the
17 -- is not a member of the subcommittee. They're not
18 deliberating with the subcommittee.

19 They are just there as a resource to
20 provide information and provide clarification.
21 That's the purpose.

22 And they are assigned essentially by the
23 -- there's a lot of factors. And what Lisa and I
24 determined in assigning, whether it's something that
25 they've already been working on, are familiar with.

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1 Whether it's -- sometimes it's just the
2 work distribution within our medical team. But as
3 far as the subcommittee itself, the make up and the
4 work distribution, that is up to -- I couldn't to the
5 -- I'd leave that to the committee to just deliberate
6 or consider for what you think a good make up is.

7 You can ask, you know, for a makeup of
8 the subcommittee. And then the work distribution of
9 the subcommittee.

10 I can just share. I know we've, you
11 know, we have working groups, right. Most of my
12 staff members are right now leading some working
13 group, one working group or another.

14 They've got working group members. They
15 distribute the work as they see appropriate.
16 Sometimes it's best just to split it up, you know,
17 equal amongst the different staff.

18 But, in the end someone has to write a
19 report. Just much like subcommittees, someone has
20 to give a presentation and write a report.

21 Who does that? I mean, that's up to the
22 subcommittee -- that's up to the subcommittee chair
23 to make that decision.

24 But that's just how we do it. I don't
25 know. I mean, I can -- I think we have some time,

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1 but I'll leave that to you all to discuss if that's
2 something you want to discuss.

3 And again, with the member make up for
4 who makes up the subcommittee. You know, we have --
5 we don't have any say in that.

6 But -- and just from my observation over
7 four and a half year, I think the committee has done
8 a good job putting the appropriate representation
9 from the different representatives on the committee
10 and the subcommittees to give it balance. Balance
11 work with the right appropriate knowledge.

12 And so that's just my -- given my
13 observation there. That's just something that the -
14 - I'll leave it to Dr. Palestro if you would like to
15 discuss that topic further.

16 CHAIRMAN PALESTRO: No. I agree. I
17 think it's really up -- distribution work is up to
18 the subcommittee, but in particular, the subcommittee
19 chair.

20 MR. BOLLOCK: Okay. One of the other
21 topics that have come up, and this is just kind of a
22 logistical thing, about an active subcommittee.

23 So, when Dr. Palestro took over, we had
24 a number of subcommittees. You know, and what makes
25 it an active committee that's still working?

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1 And what makes it, you know, what -- at
2 what point is the subcommittee done with the work? I
3 think sometimes in the past we'll have said, okay you
4 know, maybe there's a comment that the work is done.

5 But usually once a subcommittee has
6 completed their -- either their work and provided a
7 report voted on by the full committee.

8 Or they've, you know, reviewed an NRC
9 document that we've asked you to review. Such as,
10 you know, the more recent SECY papers.

11 And once that's been completed, the
12 subcommittee is essentially -- we just kind of let it
13 go. And there's nothing formally done.

14 We could make it just by practice. We
15 could make a statement that this committee's work is
16 complete. And that it's no longer a subcommittee,
17 it's just essentially disbanded.

18 And I can leave that -- again, I can give
19 some opinions on that. Or I can leave that to the
20 discretion of the ACMUI and the ACMUI chair.

21 If you have any thoughts Dr. Palestro?

22 CHAIRMAN PALESTRO: Yeah. I do. And I
23 talked to Dr. Metter who's anxious to express her
24 thoughts. So, I will defer to her.

25 VICE CHAIRMAN METTER: Thank you Dr.

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1 Palestro. I would like to have like a formal closing.
2 Because sometimes when you're chair of the committee
3 and it goes to the NRC staff, I don't know where I am
4 then.

5 And you know, so if there is a formal
6 closure and maybe a site somewhere on the -- your
7 site that you have these are the closed -- these
8 committees have been closed. These are the current
9 active committees.

10 I think that would be very helpful for
11 not only us, but the public too. To see, you know,
12 this committee maybe they would keep more -- keep
13 tabs on what's going on there.

14 I think it would be helpful to know what
15 are the committees that are still doing work and the
16 committees that are no longer -- or have completed
17 their charge.

18 CHAIRMAN PALESTRO: Well, I certainly
19 agree that formally closing the committee at the end
20 of their work should be done. And that's the end of
21 -- or the subcommittee, excuse me. And that's the
22 end of the subcommittee.

23 In terms of maintaining a list of the
24 subcommittees, I would argue that we should maintain
25 a list only of the active subcommittees. Because

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1 then the list will go on forever.

2 You know, they can certainly be archived
3 and kept for historical purposes. They may want to
4 be revisited sometimes.

5 But, in terms of our day to day or our
6 meeting to meeting work, it would be -- and I'll
7 address that in my session later on, but it would be
8 extremely useful to have the list of the active
9 committees as well as their membership.

10 MR. BOLLOCK: So, I can -- we have some
11 -- I mean, we do have some options. Right? And one
12 of the things we keep, you know, Sophie and this week
13 Lisa shared the -- our tracking list of the
14 recommendations.

15 That's one place that we can keep that
16 active list. So when we go every meeting, you'll see
17 that a committee was formed.

18 And then we'll try -- you know, we'll
19 write when it's the formal closing of it. Whenever
20 the report is done, you can formally close it.

21 And then it would close that and take
22 that off the list. But it would be on that. That's
23 one way to do it.

24 I can -- I don't know if any of my staff,
25 formally asking my coordinator who would handle most

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1 of these things if she has any thoughts? Sophie, do
2 you have any opinions on this? What you think would
3 be best?

4 MS. HOLIDAY: I have tons of opinions.

5 MR. BOLLOCK: We'd like to hear them.

6 MS. HOLIDAY: So, I recognize over the
7 last several years a lot of the feedback that we've
8 received from the committee as well as our meeting
9 attendees, and stakeholders, and staff, is that, you
10 know, more information should be shared, historical
11 information.

12 That's another reason why we have posted
13 a summarized past recommendations, so that we can
14 keep that historical knowledge. I don't see anything
15 wrong with posting subcommittees, whether they be
16 active or past subcommittees.

17 But what the past practice has been, is
18 that when a subcommittee is given a charge, and their
19 charge is usually to review something and provide
20 recommendations on something. After that
21 subcommittee has presented its recommendations to the
22 full committee, and the full committee takes its vote,
23 either they endorse or they don't endorse, and that
24 product is turned over to the staff, generally
25 speaking that is when the subcommittee's work is done.

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1 So that is when we have considered a
2 subcommittee to have completed its charge. And that
3 it can be closed.

4 I will also note with respect to the old
5 business or the recommendations and action charts,
6 where we have listed on there, subcommittees that
7 have been formed, a couple of years ago, there was a
8 request from the committee to remove those types of
9 items from the recommendation action charts.

10 That once a subcommittee had been formed,
11 we no longer had to keep it on the list. Especially
12 if that subcommittee's work had already been
13 completed.

14 Again, this information is posted on the
15 website now. Because we post all of the ACMUI's
16 recommendations. So for historical purposes, those
17 are listed.

18 So, my personal recommendation is that
19 the staff would post a list of the ACMUI
20 subcommittees. We could have a section that says
21 active subcommittees. And there could be a section
22 at the bottom that says past subcommittees or
23 something like that.

24 All of the subcommittee reports are
25 available on the ACMUI subcommittee reports' web

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1 page. We can have the link that goes directly to the
2 subcommittee reports web page.

3 Additionally, I still believe that once
4 subcommittees' report has been presented to the full
5 committee, and the full committee has taken a vote,
6 that therefore closes the subcommittee's actions.

7 For some of my older members on the
8 committee, not by age, by tenure, you will recall
9 that sometimes after a subcommittee has completed its
10 work, there have been motions from the committee to
11 reestablish -- reestablish a subcommittee based on
12 some product that the NRC staff is working on.

13 For example, patient release. That was
14 a subcommittee that was formed and was sunsetted.
15 And then we reestablished it. The Yttrium-90
16 microspheres ACMUI subcommittee did its work. Was
17 closed. Reestablished.

18 So we always have those options. So in
19 my opinion, once you have completed your charge, that
20 handing over of your subcommittee's report which then
21 is voted on and becomes a final report of the
22 committee, is the actual action of closing the
23 subcommittee.

24 I don't think that you need to actually
25 have a let's make a motion to close a subcommittee.

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1 In itself voting on the subcommittee's product is
2 closing the subcommittee.

3 CHAIRMAN PALESTRO: Yeah. I don't have
4 a strong opinion about that. But, in going through
5 some of these subcommittees, there are several older
6 subcommittees that are still being carried on the
7 books.

8 The members of which have long since
9 rotated off. So, somewhere there should be a process
10 whether we formally state that this concludes the
11 subcommittee's work and the subcommittee is formally
12 disbanded at this point.

13 Just so it's a matter of record and we
14 don't carry these subcommittees further. And if they
15 have to be reestablished, they be reestablished.
16 That's all. So, I -- and that's --

17 MS. HOLIDAY: Yes. I don't disagree with
18 that. Perhaps, you know, when the subcommittee turns
19 over its report to the full committee, while it
20 doesn't have to be captured as a formal motion on our
21 chart, because keep in mind, that chart is where you
22 get the 85 percent from.

23 It's, you know, now that we have voted
24 and approved your report, the subcommittee has
25 completed its work and maybe sunsetted. Perhaps

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1 those are the verbiage that you want to use.

2 As far as old subcommittees, the only old
3 subcommittee that I think that still exists is the
4 Medical Events subcommittee. And training
5 experience, I don't consider that old, because that's
6 fairly in its infancy.

7 But, we update those as needed.

8 CHAIRMAN PALESTRO: Okay. So you had a
9 list and can just go over in a telephone conference
10 with the group.

11 MS. HOLIDAY: Sure. Okay.

12 CHAIRMAN PALESTRO: Mr. Ouhib?

13 MEMBER OUHIB: Yeah. I just have a
14 general question probably that was addressed in the
15 past. And forgive me for that if that was done.

16 This is for Mr. Bollock. Was there any
17 consideration at any point to actually have a nursing
18 representation within the ACMUI?

19 MR. BOLLOCK: Just for clarification, you
20 mean a represent -- like another ACMUI member? Like
21 say, 14th member who's a nurse, an RN?

22 MEMBER OUHIB: Correct. Yeah. Because
23 I can't think of anybody else that spends more time
24 than anybody with a patient. And we're talking about
25 patient safety.

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1 And I can think of some medical event
2 that probably could have been prevented by nurses if
3 there was this awareness and so on.

4 DR. HOWE: I -- this is Dr. Howe. I've
5 been in the medical group since '87. And we have
6 changed the formation of the ACMUI during that period.

7 And I do not believe we have ever had the
8 consideration of adding a nurse to the committee.
9 The ones -- the new people that we have added, we've
10 added the FDA.

11 We've added the hospital administrator.
12 We've added the patient advocate. And -- well, we
13 had a diagnostic radiologist back in '86. We lost
14 him. And then we added him back.

15 We lost one of our medical physicists.
16 We added that back. But we -- in the previous to
17 '87, we didn't have a hospital administrator.

18 We didn't have a patient advocate. And
19 I don't -- no, we had a pharmacist. So that was not
20 it. But there might be three people that we did not
21 have.

22 But we've never had a consideration for
23 adding a nurse.

24 MEMBER OUHIB: I mean, the only reason I
25 bring it up is you look at, you know, the addition

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1 safety committees and all that, that are all in there.
2 And they have some input.

3 And they have some valuable information
4 that, you know, they could take to the nursing
5 basically.

6 CHAIRMAN PALESTRO: Dr. Metter?

7 VICE CHAIRMAN METTER: Thank you for that
8 comment. I think as an authorized user, you're
9 responsible for the supervision. And that would be
10 part of your team.

11 Because I think if you start adding the
12 team members, and you have to consider the nuclear
13 pharmacist and technologist and all those other
14 individuals. And, you know, and I see what you're
15 saying.

16 But I think as an authorized user, you're
17 still responsible for the supervision. So, that
18 falls under the authorized user's purview.

19 CHAIRMAN PALESTRO: Any other comments
20 or questions?

21 MS. HOLIDAY: I could also add, you guys
22 may recall Dr. Suh's subcommittee for the perfection
23 icon. At one point -- no, I'm sorry, I might be
24 mixing up subcommittees here. So many subcommittees.

25 Oh, I think it is Dr. Suh's. So, there's

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1 a recommendation that ancillary staff or nursing
2 staff return to the console or stay there throughout
3 the treatment.

4 And it was clarified during a public NRC
5 meeting that NRC does not regulate nursing staff. In
6 the past we've had conversations from the committee
7 members about adding other specialties such as
8 interventional radiologists.

9 And for those same reasons that's why
10 some of those individuals aren't represented on this
11 committee. Everybody's that sitting at this table,
12 from your physicists to your physicians, to your
13 radiation safety officer, to your pharmacist, all of
14 you guys are authorized individuals under 10 CFR part
15 35.

16 Our agreement state regulators have
17 equivalent regulations that also apply to you guys.
18 Our patient's rights advocate, her job here is to
19 make sure that whatever comes out from the committee
20 and from the NRC keeps in mind how it impacts the
21 patient.

22 Those are the individuals that I feel
23 like should be represented on this committee. I
24 didn't mean to leave you out Dr. O'Hara, and our FDA
25 partner.

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1 But these are the specialties that are
2 necessary, are applicable in our regulations. So,
3 in terms of adding a nursing staff member to the
4 committee, I'm not sure how beneficial it would be to
5 the committee.

6 Those are just my personal thoughts.

7 CHAIRMAN PALESTRO: Sophie, benefits
8 aside, if the committee felt that adding nursing, or
9 some other discipline if you will, would be useful
10 and worthwhile, how would we go about making that
11 recommendation?

12 What exactly goes on?

13 MS. HOLIDAY: Sure. So, as you guys
14 heard from Russ, we have what we call a membership
15 balance plan. Anytime that we want to change the
16 number of members on the committee or the specialties
17 or sub-specialties on the committee that has to go
18 through Commission approval.

19 So, if this is a recommendation that
20 comes from the committee, staff will, like
21 everything, have to evaluate the committee's
22 recommendations. We would have to write a paper to
23 the Commission.

24 And the Commission would have to render
25 its official decision. Because that is changing the

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1 total number for this committee.

2 Currently our charter, your charter is
3 for 13 members based on specific specialties
4 identified.

5 CHAIRMAN PALESTRO: Dr. Schleipman?

6 MEMBER SCHLEIPMAN: I would just say that
7 short of adding nursing to the table, we could
8 certainly still -- that would not preclude seeking
9 their input, counsel and so forth.

10 There's the American Nurses Association.
11 There's an OR Nurse Association. And there are
12 topics that are germane to nurses and around
13 radiation.

14 I think we can certainly still canvas and
15 solicit their opinions.

16 CHAIRMAN PALESTRO: Any other comments
17 or questions on that? Does anyone want to make a
18 motion to recommend that a nurse be appointed to the
19 committee before we move on?

20 (No response)

21 CHAIRMAN PALESTRO: All right. Thank
22 you. Back to you Mr. Bollock.

23 MEMBER OUHIB: Oh, I'm sorry. I make a
24 motion. This is Zoubir. Sorry, this is Zoubir.
25 I'll make a motion to add a nurse to the committee.

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1 CHAIRMAN PALESTRO: Thanks. Is there a
2 second?

3 (No response)

4 CHAIRMAN PALESTRO: All right. Then I
5 guess the motion dies without a second. Am I correct?

6 MR. BOLLOCK: Correct.

7 CHAIRMAN PALESTRO: I'm sorry, Ms. Weil?

8 MEMBER WEIL: I'm not sure that, you
9 know, the issue that Zoubir raises, is an interesting
10 one. And perhaps at some point in one of the meetings
11 going forward we'd like to set aside some time to
12 discuss the composition of this committee.

13 And determine if there are any
14 disciplines or constituencies that are not included.
15 And whether or not we should consider expanding or
16 changing the membership.

17 It wouldn't involve a charter revision,
18 which is no small thing. But perhaps it bears
19 discussion rather than just a simple motion on a
20 particular person and, you know, group of people.

21 CHAIRMAN PALESTRO: I think that's an
22 excellent suggestion. No, I do. I think it makes a
23 lot of sense.

24 I think it also gives us an opportunity
25 to review the current membership and decide whether

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1 or not it's appropriate as is. Whether you want to
2 add or perhaps subtract.

3 So, I would ask if we could add that to
4 the agenda for the spring meeting.

5 MS. HOLIDAY: Dr. Palestro, this is
6 Sophie.

7 CHAIRMAN PALESTRO: I'm sorry.

8 MS. HOLIDAY: Maybe what I would suggest
9 is, as the committees were every year prior, someone
10 from the team gives a presentation to the ACMUI, the
11 annual presentation to discuss the composition of the
12 ACMUI.

13 How often we meet here at headquarters.
14 If the frequency of the meetings, things like that.
15 Perhaps that would be the time where we add additional
16 time and you can discuss it in that setting.

17 Because that's something that goes along
18 with that. Are you happy with who you report to?
19 Are you happy with how the committee composition is?

20 That would be, in my opinion, the
21 appropriate. Another place that the committee could
22 discuss is, many of you, though my newer members don't
23 know, but every year we -- or every two years we do
24 the biannual evaluation.

25 And that -- there's a section on that

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1 form that says provide your comments about ways to
2 improve. Or there's also another question about do
3 you think that the current membership is
4 satisfactory, should there be changes?

5 That's another opportunity where you can
6 provide that input. And that input is directly
7 included in the staff's paper.

8 MR. BOLLOCK: Right. And this is Doug
9 Bollock. That paper's the -- the next one will be
10 next -- is due next fall.

11 So we'll be soliciting ACMUI member input
12 probably early 20 -- yeah, early 2019, spring 2019.
13 And it -- so for us to make a change to the committee
14 membership, you know, go up, add another position
15 that would take NRC Commission approval.

16 They would have to do that. And you
17 know, it is possible as Dr. Howe said, you know, in
18 her time here the membership numbers and positions
19 have changed.

20 They've, you know, some of have gone away
21 and then come back. And others have been added. So,
22 it is, you know, it can happen.

23 And actually some of the discussion and
24 what Dr. Schleipman had spoken about brings one of
25 the other topics that was brought up, the stakeholder

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1 outreach and input. Formal -- both formal and
2 informal.

3 I think, you know, seeking or getting the
4 nurses or other -- or the nuclear medic -- techs. Or
5 any of the team members input, their organizational
6 input.

7 I think that's the perfect example of
8 stakeholder, you know, informal stakeholder input
9 from you. You know, the ACMUI members bringing it
10 to us is just, you know, points that your staff or
11 your team and constituents have shared with you.

12 Or formally when we are seeking output
13 say for, you know, we just discussed the team
14 outreach. If things may affect them or if you think
15 they may have some input they can, you know, provide
16 formal input there either individually or through any
17 of their professional organizations.

18 So, that is another topic. You know,
19 that's an example of some informal or formal input
20 that came through.

21 And I do -- I know we've had discussions.
22 Dr. Alderson brought this up with the -- and it's
23 been continuing on with Dr. Palestro and Dr. Metter
24 and our stakeholder input.

25 As ACMUI members going and presenting at

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1 ACR, SMMI, ASTRO, among others. You know, we, the
2 NRC staff, we encourage that. And you know, we try
3 to participate where we can.

4 And I know Sophie has said this to you
5 members throughout the years, both in these meetings
6 and individually. You know, we encourage you all as
7 ACMUI members to bring that informal input that you
8 receive from your constituents.

9 And to, you know, to help with the
10 decision making. And to help with you being --
11 bringing your professional opinions and helping with
12 your objectivity and you know, the issues that are
13 covered here.

14 Is there any -- and I'll open it back up.
15 Is there anything else specifically that --

16 CHAIRMAN PALESTRO: Yeah. I just wanted
17 to go back again. I'm sorry Sophie, if you would
18 clarify for me again, the time when you thought it
19 would make sense to discuss considering whether or
20 not the committee should be revised, the membership.

21 MS. HOLIDAY: Sure. So, based on what
22 Ms. Weil suggested further discussions, in the
23 springtime is when the NRC gives its presentation to
24 the committee. I think I call it the annual review
25 of the ACMUI or something along those lines.

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1 And we talk about the frequency of the
2 meetings, the number of members on the committee and
3 the positions. At that time, you know, when I open
4 up for comments and discussions from the committee,
5 that could be the opportunity to bring it up if you
6 would like to discuss it further.

7 CHAIRMAN PALESTRO: Ms. Weil?

8 MEMBER WEIL: Yeah. That makes some
9 sense. It fits.

10 CHAIRMAN PALESTRO: Could I then ask that
11 staff somewhere make a little note to remind us about
12 that for the spring meeting at the time of that
13 presentation?

14 MS. HOLIDAY: Absolutely.

15 CHAIRMAN PALESTRO: Thank you. I
16 appreciate that. Mr. Bollock?

17 MR. BOLLOCK: Okay. Any other
18 discussion on stakeholder input? Formal/informal?
19 Comments, thoughts? Dr. Metter?

20 VICE CHAIRMAN METTER: Can you just go through
21 the process again of like when you have the -- for
22 the training experience she had a stakeholder initial
23 outreach, but it was limited.

24 And can you kind of go through that, what
25 the rules were? Because you had some -- a time frame

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1 on some.

2 MR. BOLLOCK: Sure. Yeah.

3 VICE CHAIRMAN METTER: And you had
4 certain goods you needed to address.

5 MR. BOLLOCK: So the -- it was because
6 of time constraints we didn't -- so when we sol --
7 when the NRC solicits input from the general public,
8 it typically requires if we're asking specific
9 questions of the public, say please give us
10 information on this.

11 It can require an OMB clearance, because
12 they have to do a review of the burden that we're
13 asking of people providing us information. There is
14 another means sometimes if it's something that falls
15 under our current regulations, we could put out a
16 Federal Register notice and ask the questions.

17 But without, you know, verifying that we
18 have to -- we have verified that we're not violating
19 the burden of course on OMB to put out a Federal
20 Register notice.

21 Because of that, to not violate OMB you
22 can solicit input from up to nine non-federal
23 entities. And that's what limited who we can go out
24 to.

25 So, for the T&E example, we went out to

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1 nine non-federal entities. And then we also reached
2 out to a number of federal entities who have license
3 and uses of the radiopharmaceuticals.

4 VICE CHAIRMAN METTER: So you just have
5 a limit on the nine non-federal. The others are up
6 to you all?

7 Or is there a total limit?

8 MR. BOLLOCK: It's just it's not a --
9 it's not considered a burden if it's other federal
10 entities. We can seek input from other federal
11 entities.

12 VICE CHAIRMAN METTER: Okay. So that
13 number is open. So there's just a limit on the num
14 -- nine non-federal.

15 MR. BOLLOCK: Right. We cannot go ten.
16 We can't go to ten or more. We can't solicit -- we
17 can't ask ten or more entities outside of -- in the
18 general public to give us information.

19 We can't request information.

20 VICE CHAIRMAN METTER: But the other
21 number is, it could be whatever you think would be
22 adequate to solicit what the greater diversity of
23 opinions?

24 MR. BOLLOCK: Well, the other number was
25 just other federal entities. So for instance we

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1 reached out to Army hospitals and -- right? So that
2 -- it's a burden -- it's a burden issue that limits
3 the numbers.

4 But it's not considered a burden if it's
5 a federal entity. It's not considered a burden for
6 us to ask another federal entity.

7 CHAIRMAN PALESTRO: Ms. Weil?

8 MEMBER WEIL: Just to clarify. This is
9 in the preliminary outreach? Not for --

10 MR. BOLLOCK: That's what limited our
11 preliminary outreach. Because we hadn't had --
12 because now we get into the time constraints.

13 We didn't have the time to verify if we
14 could get a burden review to do an OMB clearance. If
15 we needed to get that verification whether we needed
16 an OMB clearance to put out the questions.

17 MEMBER WEIL: But the expanded outreach
18 is not limited by nine non-federal?

19 MR. BOLLOCK: No.

20 MEMBER WEIL: Okay.

21 MR. BOLLOCK: We've had time to define -
22 - right. We've had time to verify that what we're
23 doing is all this. All well and good.

24 MS. DIMMICK: So if I could just add, so
25 for the outreach that we're seeking to do, we'll be

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1 doing a general solicitation for that information
2 through a Federal Register notice.

3 And once we provide a general
4 solicitation in the Federal Register, then we're not
5 bound by the number of stakeholders we can reach out
6 to, provided we're asking the same kind of information
7 that's in the general solicitation.

8 MR. BOLLOCK: Okay. Any other questions
9 on?

10 (No response)

11 MR. BOLLOCK: All right. And then the
12 last top -- specific topic that we've been asked to
13 address. And this, I know it came up on Wednesday
14 and the T&E subcommittee was asking it.

15 So how does it work for the ACMUI, NRC
16 staff, NRC management with say reviewing a report or
17 documentation? And I think there were some comments
18 from the subcommittee.

19 They actually saw the concurrence blocks
20 on our SECY paper. And it just brought the question,
21 okay, what is the process?

22 And so I can just walk the committee
23 through the process for say, you know, for our -- the
24 training experience SECY paper we just sent up to the
25 Commission.

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1 So, how the process works, typically
2 staff will write -- staff will draft the paper. And
3 then it goes through a management review.

4 And the medical teams, one of the medical
5 team members typically write it. And then it goes
6 to the medical team leader.

7 Lisa will review it and concur. And then
8 I'll review it and concur. And then our division
9 management, right now Dan Collins or Sabrina Atack,
10 will review and concur.

11 And then it will go out to -- because a
12 lot of what we do involves licensing inspection, it
13 affects the regions. So we'll send it out to the
14 regions for their review.

15 We send it to the agreement states for
16 their review. And then -- and that's the same time
17 we send it to the ACMUI for your review.

18 And then after it comes back and we've
19 addressed the comments from all three of those -- of,
20 you know our regions are the NRC. Address the
21 agreement state comments and the ACMUI comments, then
22 it goes back through -- it goes to our Office of the
23 General Counsel.

24 And then it goes to our office director.
25 And then it could possibly go to our Executive

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1 Director for Operations for signature.

2 So there's still further, our lawyers get
3 to look at it. Our senior managers get to look --
4 and then our senior managers get to look at it before
5 it goes to the Commission.

6 For those SECY papers, because ACMUI you
7 are our advisor, external advisor, your report, your
8 unfettered comments go with those SECY papers to the
9 Commission. They see exactly what you say, your
10 exact thoughts, your being the committee's, exact
11 thoughts on whatever that paper is.

12 We also have a section where we include
13 a synopsis of what the agreement states, their
14 comments on those papers. You also -- the ACMUI
15 also gets a synopsis.

16 But you're -- just the Commission has
17 asked for they want this -- the ACMUI's unfettered
18 opinion. So we also send that as well.

19 So, that's the process for say a paper
20 that's reviewed. For the 35-1000 guidance that's
21 reviewed, that goes a similar start. Typically
22 though the work is done at a working group level.

23 So, my staff -- one of my staff typically,
24 or maybe in a regional staff, will co-chair along
25 with an agreement state representative, will co-chair

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1 the working group.

2 That product goes to Lisa and I. It goes
3 to division management just for review. It goes out
4 to all the agreement states. It does to ACMUI>

5 And then it comes back. It goes to the
6 Office of General Counsel. And then goes just back
7 to our division for final approval.

8 CHAIRMAN PALESTRO: Could you repeat that
9 back to us Dr. Metter?

10 (Laughter)

11 VICE CHAIRMAN METTER: It's a long
12 process.

13 CHAIRMAN PALESTRO: Any other comments
14 or questions?

15 (No response)

16 MR. BOLLOCK: Those are the specific
17 topics that have come up in discussions we've had
18 over the past couple of months that I believe the
19 committee or subcommittee members wanted me to
20 address. Are there anything else now that we're
21 about four minutes over?

22 They like me as the DFO or just the NRC,
23 any questions for us? Or me, any you'd like to
24 address?

25 (No response)

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1 CHAIRMAN PALESTRO: Thank you.

2 MR. BOLLOCK: I think that was enough.

3 All right.

4 CHAIRMAN PALESTRO: All right. The next
5 item on the agenda is sort of continuing along with
6 the same theme. The ACMUI subcommittees,
7 subcommittee membership and the ACMUI Chair.

8 As I indicated when I was -- when we were
9 talking before, when Mr. Bollock was talking, that I
10 would like for a list of the subcommittees and their
11 members to be available for the ACMUI, along with the
12 staff liaison.

13 Or is it staff resource? What's the
14 appropriate term? I'm sorry?

15 MS. HOLIDAY: The term is synonymous.
16 Don't worry.

17 CHAIRMAN PALESTRO: I'm a creature of
18 habit. I like to see consistency. So, whatever you
19 prefer.

20 MR. BOLLOCK: So for my last three weeks,
21 it will be staff resource.

22 (Laughter)

23 CHAIRMAN PALESTRO: All right. Fine.
24 So, what I'd like to see for the committee is, as I
25 said, the list of the subcommittees and their members,

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1 along with their term expiration. As well as the
2 staff resource.

3 And I would -- I know that it will be on
4 the website. But I would appreciate it if it could
5 be mailed, email excuse me, to the committee members
6 just after each meeting or something, twice a year.

7 And on the reports of the subcommittees,
8 I think that the staff liaison's name should appear
9 on all of the reports as well as on the slide
10 presentation. So that everybody knows who they are.

11 And so that they also are acknowledged
12 for the time and effort that they put into it. We
13 do it most of the time. I don't know that we do it
14 consistently.

15 Ms. Weil?

16 MEMBER WEIL: In addition to the name --
17 the chair and the names of the subcommittee members,
18 it would be interesting to have the actual charge of
19 the subcommittee listed.

20 CHAIRMAN PALESTRO: Absolutely correct.
21 Thank you. Yeah, because it seems over time the
22 charge shifts. And it's not what it originally was.

23 So, I think that's an excellent point. I
24 apologize for that oversight.

25 All right. So, next --

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1 MS. HOLIDAY: Dr. Palestro?

2 CHAIRMAN PALESTRO: Yes, ma'am?

3 MS. HOLIDAY: Procedurally, is this a
4 motion from the ACMUI?

5 CHAIRMAN PALESTRO: Does it require a
6 motion?

7 MS. HOLIDAY: Do you want to keep it on
8 the record? Then it should come forth as a motion.

9 CHAIRMAN PALESTRO: All right. So the
10 motion is that -- the motion is the following: that
11 the members of the ACMUI be provided at least twice
12 yearly a list of the subcommittees along with the
13 specific charge or charges for the subcommittee, its
14 members and their date of termination on the
15 committee, the subcommittee, as well as the staff
16 liaison member. Staff liaison, excuse me.

17 MR. BOLLOCK: Staff resource.

18 CHAIRMAN PALESTRO: Staff resource.
19 It's been a long day Mr. Bollock. I'm sorry.

20 MR. BOLLOCK: Yeah. It's been a long
21 month.

22 CHAIRMAN PALESTRO: Ms. Weil?

23 MEMBER WEIL: The date of termination
24 might be problematic. Because if you're finishing
25 your first term, it's not known whether you're going

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1 to continue on for another term.

2 CHAIRMAN PALESTRO: But I would still
3 have it.

4 MEMBER WEIL: Okay.

5 CHAIRMAN PALESTRO: All right, I mean, I
6 think even if it is your first term, then your
7 subcommittee chair should be aware of the fact that
8 you may not be there.

9 MEMBER WEIL: Okay.

10 CHAIRMAN PALESTRO: It's just something
11 to have a guide. Because I don't -- that information
12 I don't think is readily available to us on a routine
13 basis.

14 And I'd rather have that than have
15 nothing.

16 MR. BOLLOCK: Yeah. And we have that
17 information.

18 CHAIRMAN PALESTRO: Mr. Green?

19 MEMBER GREEN: Or it would be simple
20 enough to indicate the year of termination followed
21 by a parenthesis (1), first term or (2), second term.

22 MS. HOLIDAY: There is a contact sheet
23 that normally is provided to the committee ahead of
24 the meeting that lists all of the contact information,
25 including first or second term and start date.

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1 That was not provided for this meeting.
2 But you will get it shortly after this meeting
3 concludes.

4 If I can also ask, I think I heard you
5 say, but it was not mentioned during this motion,
6 that you're also requesting that we create a web page
7 or listing for subcommittees?

8 CHAIRMAN PALESTRO: No.

9 MS. HOLIDAY: Is that also included in
10 this motion?

11 CHAIRMAN PALESTRO: No. Not at all.

12 MS. HOLIDAY: So this is just information
13 to the committee membership about members' terms and
14 contact information?

15 CHAIRMAN PALESTRO: Yeah. It's
16 information to the committee about the subcommittees'
17 membership, charge, and the members and when their
18 terms are up.

19 MR. BOLLOCK: And the staff resource.

20 (Laughter)

21 MS. HOLIDAY: But I thought earlier in
22 our discussion we said something about listing
23 something on the website for active subcommittees and
24 --

25 CHAIRMAN PALESTRO: I thought it was

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1 already on the website?

2 MS. HOLIDAY: Subcommittee reports are
3 posted on the website. Subcommittees and their
4 membership are not.

5 CHAIRMAN PALESTRO: All right. Then we
6 will -- I will amend the motion to include all of the
7 information that you're going to email us, staff is
8 going to email us, to be maintained on the website.

9 MS. HOLIDAY: If I may suggest, I think
10 I heard the motion to be, that the NRC staff will
11 provide the committee membership, just the committee
12 membership, with the information regarding the
13 member's terms and their contact information, and
14 which subcommittees they're on or the membership of
15 the subcommittees.

16 The second part of that motion is that
17 the NRC staff will create a web page that will list
18 active subcommittees and sunsetted subcommittees. I
19 believe that's the motion?

20 CHAIRMAN PALESTRO: Correct.

21 MS. HOLIDAY: Thank you.

22 CHAIRMAN PALESTRO: Is there a second?

23 UNKNOWN: Second.

24 CHAIRMAN PALESTRO: Any discussion?

25 MEMBER OUHIB: Well, I had another

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1 question. I'm not sure if we're moving.

2 Along with the charge, do we have an
3 option for a sunset date on those reports?
4 Subcommittee reports or not?

5 CHAIRMAN PALESTRO: I don't think I would
6 put that into any of that detail. I mean, we can
7 anticipate that subcommittees are going to conclude
8 its work at such and such a time.

9 But it may or may not. And I think that's
10 probably more important to the individual
11 subcommittee than to the rest of the group.

12 I mean, I think we've already got a lot
13 of information. And I don't want it to turn into a,
14 you know, into a tome.

15 I want it to be something that's easily
16 accessible to everyone. Particularly the Chair of
17 the ACMUI. Which I'm Chair now.

18 And Dr. Metter who follows me. Because
19 we're the ones ultimately responsible for putting
20 these subcommittees together and making sure that
21 they have sufficient membership.

22 And if we're going to have -- I think
23 there's already a lot of information. And I would
24 prefer not to add anything else. Unless people feel
25 strongly about that.

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1 Any other discussion?

2 (No response)

3 CHAIRMAN PALESTRO: All in favor?

4 (Show of hands)

5 CHAIRMAN PALESTRO: Any opposed?

6 (Show of hands)

7 CHAIRMAN PALESTRO: All right. It
8 passed.

9 All right, so this is a list -- excuse
10 me, this is a list. Next slide, please. No,
11 actually this is the correct slide. I'm sorry.

12 The list of the ACMUI subcommittees that
13 currently have. Are the annual review of medical
14 events; training and experience for all modalities;
15 the medical event reporting and impact on patient
16 safety culture; medical event reporting for all
17 modalities except the brachytherapy, which was
18 combined with the former patient intervention
19 subcommittee; and the patient release SECY paper
20 review.

21 In addition we created a new subcommittee
22 yesterday. So, I'd like to start with training and
23 experience for all modalities.

24 The current members are Dr. Metter, Dr.
25 Suh, Dr. Alderson who just rotated off the committee,

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1 Ms. Weil, and Ms. Shober. And Dr. Suh rotates off
2 the committee, I imagine in a few --

3 VICE CHAIRMAN METTER: And then Michael
4 Sheetz.

5 CHAIRMAN PALESTRO: Mr. Sheetz is on now?

6 MEMBER SHEETZ: I'm on there also.

7 CHAIRMAN PALESTRO: Okay. So Dr. Suh
8 rotates off the ACMUI in a couple of weeks. And Dr.
9 Alderson already rotated off.

10 So, I would like to add Dr. Ennis to
11 replace Dr. Suh. And Dr. Schleipman to replace Dr.
12 Alderson.

13 And let's just make sure, I'll check with
14 you Dr. Metter, that the charge of this committee is
15 to periodically review the training and experience
16 requirements currently in effect for all modalities,
17 and make recommendations for changes as needed.

18 Is that correct?

19 VICE CHAIRMAN METTER: It is correct.
20 Thank you.

21 CHAIRMAN PALESTRO: All right. And the
22 staff -- the staff resource or staff liaison Mr.
23 Bollock? The staff resource is Ms. Ayode.

24 All right. Let's see, can we go back?
25 I think I may have looked -- yeah, go back. Yeah.

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1 The annual review, I'm sorry, I did this
2 out of sequence. The annual review of the medical
3 events includes Dr. Ennis who's chair, Dr. O'Hara,
4 Dr. Suh, who's rotating off, Dr. Metter, Mr. Ouhib,
5 and Mr. Sheetz.

6 Is that correct?

7 VICE CHAIRMAN METTER: Yeah.

8 CHAIRMAN PALESTRO: And the charge, the
9 specific charge of this committee is to periodically
10 review trends in medical events. And to formulate
11 recommendations to reduce them.

12 And the staff?

13 MR. BOLLOCK: It's Dr. Howe.

14 CHAIRMAN PALESTRO: Dr. Howe.

15 MEMBER GREEN: Dr. Palestro, I'm not sure
16 if this is a onetime consult, but I was asked and
17 looked up the information on 35, part 200 for this
18 subcommittee.

19 CHAIRMAN PALESTRO: For which
20 subcommittee?

21 MEMBER GREEN: For the medical events.
22 And that was presented yesterday.

23 CHAIRMAN PALESTRO: Were you -- I don't
24 believe I added you to the committee.

25 VICE CHAIRMAN METTER: It's six to five.

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1 CHAIRMAN PALESTRO: Let's see, Dr. Suh,
2 one, two, three, four, five. So then Mr. Green, I
3 will add you. And Dr. Suh is rotating off.

4 All right. Then there are several
5 subcommittees that I believe are ready to be
6 disbanded. That would be the next slide, please.
7 Can we go back one? Okay.

8 Medical event reporting and impact on
9 patient safety culture; the medical event reporting
10 for all modalities except the brachytherapy combine
11 -- which is combined with the former patient
12 intervention subcommittee; the patient release SECY
13 paper review; and the Y-90 microspheres.

14 These subcommittees have all completed
15 their tasks. And as I said, on several of these
16 subcommittees, the members have already rotated off.

17 Any questions about that?

18 (No response)

19 CHAIRMAN PALESTRO: Sophie, do we need a
20 motion to -- no? Okay.

21 MS. HOLIDAY: Dr. Palestro, if I could
22 go back just to the training and experience for all
23 modalities subcommittee slide.

24 CHAIRMAN PALESTRO: Yes.

25 MS. HOLIDAY: I don't think you mentioned

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1 Mr. Michael Sheetz. He was added to the
2 subcommittee. So you currently just - you're fine
3 with membership numbers.

4 But this is six individuals total. So
5 we will now have Dr. Metter as the chair, Dr. Ennis
6 to replace Dr. Sun, Dr. Schleipman, Ms. Laura Weil,
7 Ms. Shober, and Mr. Sheetz.

8 CHAIRMAN PALESTRO: And that brings us
9 to six total?

10 MS. HOLIDAY: Six total.

11 CHAIRMAN PALESTRO: Well, as you see as
12 I'm going through this, I think I'm the best example
13 as to why we should have a list of subcommittee
14 members.

15 Because going back and forth in emails,
16 and I obviously have not kept track of it the way I
17 should.

18 But, thank you Ms. Holiday. All right.
19 Next slide, please.

20 Additional subcommittees to be ended or
21 sunsetted as you prefer. The physical presence
22 requirements for the Leksell Gamma Knife Icon; the -
23 - I guess that's the last, no I'm sorry, the Nursing
24 Mothers Guidelines, which is on the next slide.

25 And that is it. Dr. Schleipman?

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1 MEMBER SCHLEIPMAN: Your previous slide
2 also had a Germanium Gallium 68 there.

3 CHAIRMAN PALESTRO: That is a mistake.

4 MEMBER SCHLEIPMAN: Okay.

5 CHAIRMAN PALESTRO: Okay?

6 MEMBER SCHLEIPMAN: Okay.

7 CHAIRMAN PALESTRO: So for the Gallium
8 68 -- or before we get to that, any discussion about
9 those subcommittees?

10 As I say, they've all completed their
11 charges. The reports have been submitted and
12 accepted by the full ACMUI.

13 All right. Ms. Holiday, any? Okay.
14 All right, so let's go to the Germanium 68, Gallium
15 68 licensing guidance.

16 Ms. Shober is chair, Mr. Sheetz, Dr.
17 Metter, Dr. Martin, I'd like to have on that
18 subcommittee. Staff?

19 MR. BOLLOCK: Dr. Daibes.

20 CHAIRMAN PALESTRO: Next slide. All
21 right, I need to form a subcommittee to review and
22 comment on the Regulatory Guide 8.39, the release of
23 patients administered radioactive materials.

24 I would ask that Mr. Sheetz chair this
25 committee.

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1 MEMBER SHEETZ: I'd be glad to.

2 CHAIRMAN PALESTRO: Members, Ms. Shober,
3 Dr. Dilsizian, Dr. Schleipman, and Dr. Martin.
4 Staff?

5 MR. BOLLOCK: Dr. Daibes.

6 MS. HOLIDAY: Dr. Palestro?

7 CHAIRMAN PALESTRO: Yes, ma'am?

8 MS. HOLIDAY: May I also ask as since
9 this is related to patient release, might you consider
10 your patient's rights advocate?

11 Or is this because her -- keeping in mind
12 that her term will be up next August.

13 (Laughter)

14 CHAIRMAN PALESTRO: Ms. Weil, would you
15 agree to join the committee for the remainder of --
16 that subcommittee for the remainder of your time?
17 Thank you.

18 And then the Yttrium-90 -- I'm sorry.
19 Mr. Ouhib?

20 MEMBER OUHIB: Yeah. Just a comment on
21 the release of patients administered radioactive
22 material. Is there a representation on therapy and
23 all that?

24 Has that been looked at? And
25 brachytherapy?

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1 CHAIRMAN PALESTRO: I'm sorry, you lost
2 me.

3 MEMBER OUHIB: So, what are we talking
4 about? What radioactive materials are we talking
5 about? I just want to make sure that there's a
6 representation within the --

7 CHAIRMAN PALESTRO: I believe this is the
8 release of patients who have received unsealed
9 sources. Is that correct?

10 MR. BOLLOCK: Correct. And it's all --
11 it's our guidance for all. Yeah, it's all

12 MEMBER OUHIB: All?

13 MR. BOLLOCK: Um-hum.

14 MEMBER OUHIB: That means if you have a
15 prostate implant and the patient was released, that's
16 one of them. Is that correct?

17 MR. BOLLOCK: Correct. It's -- yeah.

18 MEMBER OUHIB: Okay. I think my
19 question, is there a good representation within that
20 committee that can address all of those? That's all.

21 CHAIRMAN PALESTRO: Okay. Well, I'll
22 ask the members of the subcommittee. Dr. Martin?

23 MEMBER MARTIN: Sure.

24 CHAIRMAN PALESTRO: All right.
25 Acceptable to you Mr. Ouhib?

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1 MEMBER OUHIB: Yes. Thank you.

2 CHAIRMAN PALESTRO: Right. No, thank
3 you for bringing it to my attention.

4 Again, you know, if this points out
5 nothing else, it certainly points out how to me, how
6 difficult it is to try to put the subcommittees
7 together and get the appropriate individuals. But
8 maybe that's just my limitation.

9 Okay. For the regulatory guideline and
10 the release, Mr. Sheetz is chair. The members are
11 Ms. Shober, Dr. Dilsizian, Dr. Schleipman, Dr.
12 Martin, and Ms. Weil.

13 Next is the Yttrium-90 microspheres.
14 Which on the slide I have, is not slated to be formed
15 until late 2019. But I believe that it's due earlier
16 at this point.

17 Am I correct based on the discussions of
18 this morning?

19 MR. BOLLOCK: Yes.

20 CHAIRMAN PALESTRO: So, we really should
21 form that subcommittee now.

22 MR. BOLLOCK: Yeah. You can form the
23 subcommittee to be standing by to review the document
24 when staff's ready to provide it.

25 CHAIRMAN PALESTRO: Okay. All right.

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1 Then for the subcommittee whose charge will be to
2 review and make recommendations on the Yttrium-90
3 microspheres, and so it's going to be a regulatory
4 guidance.

5 MR. BOLLOCK: Yes. This is 35-1000
6 licensing guidance.

7 CHAIRMAN PALESTRO: Okay. I'm going to
8 ask Dr. O'Hara to chair this committee. Membership
9 will be Dr. Dilsizian, Mr. Ouhib, Dr. Martin, and Dr.
10 Schleipman.

11 MS. HOLIDAY: May I ask if a radiation
12 oncologist will be on the committee? Or if your
13 diagnostic radiologist would be on the subcommittee?

14 This is to provide comments on the
15 staff's draft guidance, correct? AU Training.

16 CHAIRMAN PALESTRO: Then I'm going to ask
17 that Dr. Metter also be a member of this committee.

18 VICE CHAIRMAN METTER: Delighted.

19 MS. HOLIDAY: Just to recap, I have Dr.
20 O'Hara as the chair, Dr. Dilsizian, Mr. Ouhib, Ms.
21 Martin, and Dr. Metter?

22 CHAIRMAN PALESTRO: And Dr. Schleipman.

23 MS. HOLIDAY: And Dr. Schleipman.

24 MEMBER OUHIB: So Ms. Holiday, were you
25 requesting a radiation oncologist on that group? Is

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1 that what you were asking?

2 MS. HOLIDAY: I was just asking the
3 Chairman if he would like to consider adding a
4 radiation oncologist. If he chose not to, that's
5 perfectly fine.

6 CHAIRMAN PALESTRO: Yeah. And Ms.
7 Holiday raised a good point. And my rationale for
8 selecting the radiologist is that in the vast
9 majority of cases, they are the individuals
10 administering these agents, the microspheres.

11 And that's my rationale for that.

12 MEMBER OUHIB: That's debatable.

13 CHAIRMAN PALESTRO: Okay. Well, correct
14 me if I'm wrong Ms. Holiday, but in this case the
15 Chair has the final word?

16 MS. HOLIDAY: That is correct.

17 CHAIRMAN PALESTRO: Thank you.

18 (Laughter)

19 CHAIRMAN PALESTRO: Any other comments
20 or questions? Mr. Bollock?

21 MR. BOLLOCK: And Dr. Palestro, if you
22 may. I can speak to the Gallium/Germanium generator
23 subcommittee like why, what the confusion was there.

24 So, and it brings back a point --

25 CHAIRMAN PALESTRO: I'm sorry, before we

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1 get to that, staff?

2 MR. BOLLOCK: Staff will be Dr. Tapp.

3 CHAIRMAN PALESTRO: Thank you.

4 MR. BOLLOCK: Okay. And I know you all
5 have your ethics training yesterday. Well, one of
6 the members already used his ethics beforehand. So,
7 Mr. Richard Green has recused himself from the
8 Germanium/Gallium generator review.

9 So, we had to -- there was some -- so the
10 subcommittee had to be formed. We originally thought
11 the subcommittee would be formed with our nuclear
12 pharmacist. Right? That makes sense.

13 Unfortunately he did recognize that it
14 could be a conflict. Brought it to the NRC staff's
15 attention. We made sure just to, in good conscience
16 that it was the right thing to do to have him recuse
17 himself.

18 And that's why we had to reform the
19 committee. And there's some -- that's why the slides
20 were off with what was supposed to be done.

21 So the new subcommittee will review the
22 staff's draft guidance. And then present to the full
23 committee.

24 And we'll be setting up, whenever the
25 subcommittee is ready to present, we'll set up a

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1 public teleconference in the next few months.

2 CHAIRMAN PALESTRO: Yes. I would hope
3 to hold a telephone conference review rather than
4 waiting until the spring. I don't think we need to
5 wait that long.

6 Are you agreed Ms. Shober? You're chair.

7 MEMBER SHOBER: I agree.

8 CHAIRMAN PALESTRO: All right. Any
9 other comments or questions?

10 (No response)

11 CHAIRMAN PALESTRO: All right. And I
12 skipped around a little bit. I want to go back to
13 the bylaws committee. Okay?

14 And we reviewed the bylaws a couple of
15 years ago. But I would like to have them reviewed
16 again.

17 The specific charge for this subcommittee
18 is to review and update the bylaws as needed with
19 specific attention to the role of the ACMUI Chair on
20 the subcommittees.

21 The reason why I am raising this issue is
22 because I was the chair of the subcommittee on
23 training and experience. And I was informed that
24 when I became Chair of the ACMUI that I had to give
25 up that position.

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1 And I originally understood that those
2 were part of the rules and regulations. And it
3 eventually came to be that it really wasn't rules and
4 regulations, but more tradition with a good purpose
5 obviously.

6 To ensure that the Chair of the entire
7 committee doesn't exert undue influence. Or in
8 colloquial terms, strong-arm the subcommittee.

9 (Laughter)

10 CHAIRMAN PALESTRO: Which, I guess is
11 fine. I had a vested interested for those of you who
12 have been on the committee of several years, know
13 that I was chair and actively involved and had the
14 pleasure of presenting to the Commission a couple of
15 times on this topic.

16 And I don't have an answer as to what the
17 role of the ACMUI Chair should or should not be. My
18 own personal opinion is that it should be defined one
19 way or another rather than left up to, well you really
20 shouldn't, but you could.

21 But it's just I need rules for my life
22 personally.

23 (Laughter)

24 CHAIRMAN PALESTRO: I may not like them.
25 But I can live by the rules. And I just find it

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1 difficult not to have that sort of guidance.

2 So, Ms. Weil is going to chair this
3 subcommittee. Dr. Schleipman, I ask that you be on
4 this committee. And I've got to find the -- oh, Ms.
5 Shober, and Ms. Sheetz.

6 Ms. -- I'm sorry, I apologize Mr. Sheetz.

7 (Laughter)

8 MEMBER SHEETZ: Whatever. I was just
9 looking behind me.

10 CHAIRMAN PALESTRO: And now a couple of
11 comments for the subcommittee. Neither Dr. Metter
12 nor I, are going to participate in any of the
13 discussions.

14 Okay? I want it to be arm's length.
15 This is really up to the subcommittee to form their
16 opinion.

17 And so we're not going to participate in
18 any of the discussions. Nor are we going to
19 participate in any voting on your final
20 recommendations.

21 And then finally, assuming that it
22 doesn't -- that it's not a transgression of the rules
23 and regulations, whatever decision you make will
24 become effective the time I rotate off as Chair. All
25 right.

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1 I'd like it to be as much at arm's length
2 as possible. I think it's -- at least to me it's
3 important that that be formalized in one way or
4 another.

5 Any comments or questions? Yes, Dr.
6 Schleipman?

7 MEMBER SCHLEIPMAN: Oh, yeah. I do have
8 a resource?

9 MR. BOLLOCK: The staff resource will be
10 Sophie Holiday for now. That may change when I'm --
11 when we get an ACMUI coordinator. And it will be --
12 that will be the staff resource.

13 So for now Sophie Holiday.

14 CHAIRMAN PALESTRO: Any other comments
15 or questions? Concerns?

16 (No response)

17 CHAIRMAN PALESTRO: Ms. Holiday,
18 anything?

19 MS. DIMMICK: Since in this session we're
20 discussing the subcommittees that are being formed
21 during this meeting, if you just want to revisit the
22 medical event report subcommittee that was formed
23 yesterday. That committee, the members in there.

24 CHAIRMAN PALESTRO: I don't have the list
25 of new --

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1 MS. DIMMICK: Oh. So for the -- so the
2 subcommittee on reporting medical event reports, Dr.
3 Ennis is the chair. Ms. Weil, Dr. Martin, Ms. Shober,
4 Mr. Ouhib, and Dr. Dilsizian.

5 CHAIRMAN PALESTRO: Staff?

6 MS. DIMMICK: And the staff resource is
7 me, Lisa Dimmick.

8 CHAIRMAN PALESTRO: All right. Any
9 other questions or comments on this topic?

10 (No response)

11 CHAIRMAN PALESTRO: All right. Then I'm
12 going to turn this over, the meeting over to Ms.
13 Dimmick for the final session the Administrative
14 Closing.

15 MS. DIMMICK: Okay. I'm going to do the
16 Administrative Close my way. And so -- and capture
17 the items.

18 So, at the close of this meeting, we --
19 the Chairman, Chairman Palestro established five
20 subcommittees or five new subcommittees.

21 And they are a medical event reports
22 subcommittee; the regulatory guide 8.39 release of
23 patients subcommittee; the Yttrium-90 microspheres
24 licensing guidance subcommittee; the Germanium
25 68/Gallium 68 licensing guidance subcommittee; and a

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1 bylaw's subcommittee.

2 Okay. Catching up to where the motions
3 were. There was a -- the committee, a motion was
4 made to approve the nursing mothers' guidelines
5 report. That was seconded and approved unanimously
6 or endorsed by the full committee, all in favor.

7 That report was then also appended with
8 a motion made to add language to the report to
9 indicate that the radiopharmaceuticals identified in
10 that report were as of this date. And that included
11 known radiopharmaceuticals as the date of that
12 report.

13 So that motion was seconded and
14 unanimously approved to add that language to the
15 nursing mothers' guideline report.

16 A motion was made to approve the Gamma
17 Knife physical presence requirements licensing
18 guidance. It was seconded and approved unanimously
19 by the full committee.

20 The ACMUI requested a few administrative
21 items of staff. One being for staff to provide a
22 list of all the ACMUI members and the categories that
23 they represent along with their contact information
24 so that all committee members had that access, that
25 information available to them.

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1 The committee also requested that the NRC
2 staff provide a copy of the AARM agency action review
3 meeting slide on Yttrium-90, as well as the business
4 line meeting slides that -- where we presented a
5 report of Yttrium-90 as well, to the ACMUI for the
6 medical event reporting -- for the medical event
7 subcommittee.

8 We'll provide it to the full committee.
9 But, there were specific committees that requested
10 that information.

11 We also -- a request was for NRC to
12 consider if it could draft an information notice on
13 best practices for certain medical events that were
14 described in the medical events subcommittee report.

15 And last, the April -- the spring
16 meeting, the dates that -- our first choice are April
17 15 and 16. And the second choice dates as the
18 alternate are April 3 and 4.

19 And I believe that's all the action items
20 that the committee voted to approve and/or
21 subcommittees that were appointed and additional
22 action items.

23 CHAIRMAN PALESTRO: Thank you. Any
24 other business? Questions, comments? Anybody have
25 anything they'd like to say before we adjourn?

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1 MS. DIMMICK: Sophie has a question. Did
2 I --

3 MS. HOLIDAY: The -- I have a question
4 regarding one of the items that you just said Lisa,
5 regarding the medical event subcommittee's
6 recommendation for the information notice.

7 Was that formally a motion made by the
8 committee? Because as I understand, that was a
9 recommendation from the subcommittee.

10 But it did not come forth as a motion
11 from the committee. Am I correct?

12 MS. DIMMICK: That's what I have in my
13 notes.

14 MS. HOLIDAY: That it came from the
15 committee?

16 MS. DIMMICK: No. It did not come --
17 that the subcommittee commented on it for NRC to
18 consider an information notice.

19 But there was not a formal motion made
20 for NRC to develop an information notice on best
21 practices.

22 MS. HOLIDAY: Okay. Then I will have to
23 ask if there is a motion from the committee?

24 CHAIRMAN PALESTRO: Is there a motion?

25 MEMBER SUH: I make a motion.

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1 CHAIRMAN PALESTRO: Second?

2 UNKNOWN: Second.

3 CHAIRMAN PALESTRO: Any discussion?

4 (No response)

5 CHAIRMAN PALESTRO: All in favor?

6 (Show of hands)

7 CHAIRMAN PALESTRO: Any opposed?

8 (Show of hands)

9 MS. HOLIDAY: Okay. Thank you. And
10 then I'm also going to follow up on the items that
11 Lisa said. Just like you, I need order. So, for the
12 subcommittees, I'd just like to go over the
13 membership.

14 So as I have noted, Dr. Palestro amended
15 the training and experience for all modality
16 subcommittee membership to now include Dr. Metter as
17 the chair, Dr. Ennis, Dr. Schleipman, Ms. Weil, Ms.
18 Shober, and Mr. Sheetz.

19 Are there any questions and comments on
20 that?

21 (No response)

22 MS. HOLIDAY: Okay. Then I have the
23 second item. Dr. Palestro created the
24 Germanium/Gallium 68 licensing guidance subcommittee
25 to include Ms. Shober as the chair, Dr. Metter, Ms.

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1 Sheetz, and Ms. Martin.

2 The staff resource is Dr. Said Daibes.
3 And this subcommittee will plan to have a -- or the
4 ACMUI will plan to have a public teleconference in
5 the near future to be determined at a later date.

6 Are there any questions and comments on
7 that?

8 (No response)

9 MS. HOLIDAY: Then the next subcommittee
10 that I have is the regulatory guide 8.39 release of
11 patients administered radioactive materials. I have
12 Mr. Sheetz as the chair, Ms. Shober, Dr. Dilsizian,
13 Dr. Schleipman, Ms. Martin, and Ms. Weil.

14 Dr. Daibes is NRC staff resource. Are
15 there any questions and comments on that?

16 (No response)

17 MS. HOLIDAY: Okay. And then I have the
18 Yttrium-90 microspheres brachytherapy licensing
19 guidance subcommittee. Dr. O'Hara will be the chair,
20 Dr. Dilsizian, Mr. Ouhib, Ms. Martin, Dr. Metter and
21 Dr. Schleipman.

22 NRC staff resource is Dr. Katie Tapp.
23 Are there any questions or comments on that?

24 (No response)

25 MS. HOLIDAY: Okay. And then I have the

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1 ACMUI bylaw subcommittee. The charge of that
2 subcommittee is to review and update the bylaws as
3 needed with specific attention to the role of ACMUI
4 Chair and his or her participation on subcommittees.

5 This subcommittee will be chaired by Ms.
6 Weil. Additional members are Dr. Schleipman, Ms.
7 Shober, and Mr. Sheets.

8 NRC staff resource is myself. Are there
9 any questions or comments about that?

10 CHAIRMAN PALESTRO: Yes. I just want to
11 -- I'm sorry. I just want to add that the review of
12 the bylaws isn't limited just to the role of the ACMUI
13 Chair.

14 But I want to make sure that that's
15 covered as part of your review. So feel free to make
16 any other recommendations for change as you see fit.

17 MS. HOLIDAY: Okay. And then I believe
18 the last subcommittee that I have noticed is the
19 subcommittee that was formed yesterday for the
20 medical events subcommittee. Medical event reporting
21 subcommittee.

22 The chair will be Dr. Ennis. Additional
23 members are Ms. Weil, Ms. Martin, Mr. Ouhib, and Dr.
24 Dilsizian.

25 NRC staff resource is Dr. Donna Beth

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1 Howe. No? Is --

2 MS. DIMMICK: She's another committee.

3 MS. HOLIDAY: Ms. Lisa Dimmick.

4 MS. DIMMICK: Yes.

5 CHAIRMAN PALESTRO: It's not the medical
6 event reporting committee, because that's already in
7 existence. I don't --

8 MS. DIMMICK: It's the committee that's
9 going to look at the medical event, the information
10 in medical event reports.

11 MS. HOLIDAY: Okay.

12 MS. DIMMICK: Okay.

13 VICE CHAIRMAN METTER: Excuse me Sophie,
14 I think -- can you go over that list again of the
15 members for that last committee?

16 MS. HOLIDAY: Sure. I have Dr. Ennis as
17 the chair, Ms. Laura Weil, Ms. Melissa Martin, Mr.
18 Zoubir Ouhib, and Dr. Vasken Dilsizian.

19 MEMBER SHOBER: And Megan Shober.

20 MS. HOLIDAY: And Megan Shober.

21 VICE CHAIRMAN METTER: And Megan Shober,
22 yes.

23 MS. HOLIDAY: With NRC staff resource as
24 Ms. Lisa Dimmick. Okay. Are there any further
25 questions or comments on that?

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1 MS. DIMMICK: Not on that Sophie. I did
2 have two items I did not mention. So, for the
3 administrative close that I've omitted, I'll add
4 those now.

5 So, a motion was made to provide a list
6 of all the subcommittees, their members, the
7 expiration of the member's terms, and as well as the
8 charge for each subcommittee to provide a list of
9 that information to all of the members.

10 And in addition, it was to create a web
11 page that included the current subcommittee
12 information as well as sunsetted committees on the
13 NRC web page.

14 So that motion was seconded and approved
15 by all committee members. So that will be another
16 recommendation that will appear on the 2018
17 recommendation chart.

18 The other thing I wanted to note, at the
19 request of the committee that in the spring we will
20 be doing the annual review of the committee meetings
21 and memberships.

22 And at that time we'll remind the ACMUI
23 members that we're going to hold that session in that
24 spring meeting so the committee can be prepared to
25 talk about changes to membership.

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1 I think that is all that I have on my
2 notes.

3 MS. HOLIDAY: And I have one final item.
4 Is that the ACMUI tentatively planned to hold its
5 spring 2019 meeting with the first choice being April
6 15 and 16. With the backup date of April 3 and 4.

7 MS. DIMMICK: Yes.

8 MS. HOLIDAY: Thank you.

9 MS. DIMMICK: I did.

10 MS. HOLIDAY: Sorry.

11 CHAIRMAN PALESTRO: All right. Any
12 other business?

13 (No response)

14 CHAIRMAN PALESTRO: We're adjourned.
15 Thank you all. I'm sorry, Mr. Bollock?

16 MR. BOLLOCK: I was just -- it's a
17 privilege being on the committee. I was just going
18 to introduce Chris Einberg is going to be my
19 replacement.

20 Many of you members remember Chris when
21 he was in this role four and a half years ago before
22 I took it over. And Chris is taking it back when I
23 depart.

24 So I know Chris has gone around and
25 introduced himself to many of the new members. But,

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1 for everyone's awareness, that's in person there is
2 Chris.

3 MR. EINBERG: Yeah. Thanks Doug. You
4 know, so four and a half years ago Doug took over.
5 And I'd like to thank Doug for his excellent service,
6 for serving as the ACMUI Coordinator or the Branch
7 Chief for the Source -- or the Medical Safety Events
8 Assessment Branch.

9 And so I think he's done a great job. I
10 know many of you from when I was here. I hired many
11 of you or I was in the interview process with many of
12 you.

13 So, I look forward to working with all of
14 you again. And getting to know the new staff here.

15 So, we'll be working together. And so
16 all the best. Thanks.

17 MR. BOLLOCK: Thanks Chris.

18 CHAIRMAN PALESTRO: Anything else?

19 MR. BOLLOCK: No. Close the meeting.

20 CHAIRMAN PALESTRO: All right. Thank
21 you. The meeting is adjourned.

22 (Whereupon, the above-entitled matter
23 went off the record at 2:46 p.m.)

24

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