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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

+ + + + +

THURSDAY,

MARCH 8, 2018

+ + + + +

The meeting was convened in room T2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:34 a.m., Philip Alderson, ACMUI Chairman, presiding.

MEMBERS PRESENT:

- PHILIP O. ALDERSON, M.D., Chairman
- VASKEN DILSIZIAN, M.D., Nuclear Cardiologist
- RONALD D. ENNIS, M.D., Radiation Oncologist
- DARLENE F. METTER, M.D., Diagnostic Radiologist
- MICHAEL O'HARA, Ph.D., FDA Representative
- CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician
- JOHN J. SUH, M.D., Radiation Oncologist
- LAURA M. WEIL, Patients' Rights Advocate
- PAT B. ZANZONICO, Ph.D., Vice Chairman

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1       NON-VOTING MEMBERS PRESENT:

2                   RICHARD GREEN

3                   ZOUBIR OUHIB

4                   MEGAN SHOBER

5

6       NRC STAFF PRESENT:

7                   MARC DAPAS, Director, Office of Nuclear

8                   Materials Safety and Safeguard (NMSS)

9                   LINDA HOWELL, Acting Deputy Director, Division

10                  of Materials Safety, Security, States, and

11                  Tribal Programs (MSST)

12                  DOUGLAS BOLLOCK, ACMUI Designated Federal

13                           Officer

14                  SOPHIE HOLIDAY, ACMUI Alternate Designated

15                           Official and ACMUI Coordinator

16                  MARYANN AYOADE, NMSS/MSTR/MSEB

17                  JENNIFER BISHOP, R-III/DNMS

18                  RUSSELL CHAZELL, SECY/RAS

19                  SAID DAIBES, Ph.D., NMSS/MSST/MSEB

20                  LISA DIMMICK, OEDO

21                  SARA FORSTER, R-III/DNMS

22                  ROBERT GALLAGHAR, R-I/DNMS

23                  MICHELLE HAMMOND, R-IV/DNMS

24                  LATISHCA HANSON, R-IV/DNMS

25                  PATRICIA HOLAHAN, Ph.D., NMSS/DRM

26       NRC STAFF PRESENT (CONT.):

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1 VINCENT HOLAHAN, Ph.D., NMSS/MSST  
2 ESTHER HOUSEMAN, OGC/GCLR/RMR  
3 DONNA-BETH HOWE, Ph.D., NMSS/MSST/MSEB  
4 KEVIN NULL, R-III/DNMS  
5 PATTY PELKE, R-III/DNMS  
6 GRETCHEN RIVERA-CAPELLA, NMSS/MSST/MSEB  
7 DIANE SIERACKI, OE/CRB  
8 ZAHID SULAIMAN, R-III/DNMS  
9 KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB  
10 IRENE WU, NMSS/MSST/MSEB  
11 SHIRLEY XU, NMSS/MSST/MSLB  
12

13 MEMBERS OF THE PUBLIC PRESENT:

14 DAVE ADLER, American Society of Radiation  
15 Oncology (ASTRO)  
16 ROBERT DANSEREAU, New York State Department  
17 of Health  
18 MIGUEL DE LE GUARDIA, Cook's Children Medical  
19 Center  
20 LYNNE FAIROBENT, *unaffiliated*  
21 CAITLIN KUBLER, Society of Nuclear Medicine  
22 and Molecular Imaging  
23 MELISSA MARTIN, American Association of  
24 Physicists in Medicine (AAPM)  
25 RICHARD MARTIN, AAPM

26 MEMBERS OF THE PUBLIC PRESENT (Cont.):

27 MICHAEL PETERS, American College of Radiology

1 JOSEPHINE PICCONE, *unaffiliated*  
2 A. ROBERT SCHLEIPMAN, Partners Healthcare  
3 CINDY TOMLINSON, ASTRO

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1

2

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

3

(8:34 a.m.)

4

5

6

MR. BOLLOCK: Good morning everyone and thanks to Dr. Alderson. We'll kick off the second day of the ACMUI Meeting.

7

8

9

10

To begin the day we will start with a special presentation to Dr. Zanzonico from Mr. Marc Dapas, our Office Director in the Office of Nuclear Material and Safeguard.

11

12

13

MR. DAPAS: Thanks, Doug. Boy, I appreciate the opportunity to spend a few moments here in paying a tribute to the services of Dr. Zanzonico.

14

15

16

17

Let me just highlight a couple of things regarding the contributions that you have made to this group over the time that you've served as a member of the ACMUI.

18

19

20

21

You began service on the ACMUI in March of 2010. You were renewed for a second term in 2014 and then appointed as the ACMUI Vice Chairman in October of 2015.

22

23

24

25

And Dr. Zanzonico has briefed the Commission during a number of Commission and ACMUI meetings on several occasions. Starting out in October of 2013, I know you talked to the Commission

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1 about ACMUI's comments on the expanded Part 35  
2 rulemaking.

3 And then have had quite a bit of  
4 involvement with the patient release of project. Back  
5 in May of 2014, you presented the ACMUI's position on  
6 patient release and then in March of 2016, I  
7 understand that you provided ACMUI's comments on the  
8 patient release project and the activities of the NRC.

9 And then today, as I understand it, at the  
10 Commission meeting this morning, you will be  
11 discussing the ACMUI's comments on our recommendations  
12 for revisions to the patient release program. And I  
13 signed the Commission paper that was provided,  
14 recommending that we, or indicating that we plan to  
15 update guidance versus pursue rulemaking for patient  
16 release.

17 And I appreciate very much the ACMUI's  
18 engagement on that important topic. The topic of  
19 considerable stakeholder interest. And thank you,  
20 Dr. Zanzonico, I hope I'm pronouncing that correctly -  
21 -

22 VICE CHAIRMAN ZANZONICO: That's fine.

23 MR. DAPAS: -- for your involvement in  
24 that effort.

25 Clearly you are recognized for your

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1 expertise in the field of medical physics and nuclear  
2 medicine, and as a result of that recognized expertise  
3 you had the opportunity to serve as vice chairman.

4 You also served on the speaker panel for  
5 the NRC medical issues workshop in June of 2011. And  
6 during your time on the ACMUI you have, the staff has  
7 benefitted from your expertise on a number of high  
8 priority issues.

9 Including the review of the hormesis  
10 linear no threshold petitions for rulemaking. And  
11 it's my understanding there was a meeting most  
12 recently on the National Council on Radiological  
13 Protection earlier this week where they talked about  
14 the linear no threshold model.

15 But certainly appreciate your views  
16 regarding our actions to consider whether we wanted to  
17 pursue rulemaking with respect to that model.

18 The advanced notice of proposed rulemaking  
19 on potential changes to radiation protection  
20 regulations embodied in Part 20. You've been involved  
21 in providing your perspective on the release of  
22 patients administered radioactive materials, as I  
23 mentioned.

24 And then revisions to NUREG-1556 Volume 9,  
25 which is consolidated guidance about materials,

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1 licenses and program specific guidance about medical  
2 use licenses.

3 And then Part 35.1000, dealing with  
4 licensing guidance for Germanium-68 and Gallium-68  
5 generators, in the impact of decommissioning funding  
6 plan requirements on the use of those particular  
7 generators.

8 And then finally, we have benefitted from  
9 your expertise on nursing mother guidelines for the  
10 medical administration of radionuclides. I think  
11 there was a subcommittee report out on that earlier  
12 this week in a public meeting with folks participating  
13 via phone on that matter.

14 And you also served as chair to five  
15 subcommittees including ACMUI bylaws, licensing of  
16 Radium-223 Dichloride, Germanium-68/Gallium-68  
17 generator licensing guidance, as I mentioned.

18 And both the proposed rule and final rule  
19 for the medical use of byproduct material. Meaning,  
20 medical event definitions, training and experience and  
21 clarifying amendments in Parts 30, 32 and 35.

22 And I know, from my time in the regional  
23 office and then of course my time here in NMSS, there  
24 has been a lot of engagement on medical event  
25 definitions in the brachytherapy as well as training

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1 and experience requirements.

2 And I appreciate the efforts of the ACMUI  
3 in looking at the competency modeling versus just the  
4 hours approach and we look forward of course to the  
5 Committees views on how to proceed with respect to  
6 that. And your willingness to look at various  
7 modalities in determining what are the appropriate  
8 training and experience requirements.

9 But I would like to, at this time, take  
10 the opportunity to just present you with a few items  
11 to express our appreciation and gratitude for your  
12 eight years of dedicated service, Dr. Zanzonico. And  
13 thank you, again, for all the input that you've  
14 provided.

15 I do view this committee as a very  
16 important aspect to our process and that the input you  
17 provide, the perspectives that you offer certainly  
18 help to shape our approaches to the regulatory  
19 products that we provide. And we very much value the  
20 expertise on this Panel.

21 And that expertise is particularly  
22 embodied with the efforts and perspective that you've  
23 offered over your eight years of involvement,  
24 Dr. Zanzonico. So with that, let me first begin with,  
25 and please feel free to come up here.

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1                   What I first would like to present you  
2 with this gold lapel pin. That's just a token of our  
3 appreciation.

4                   VICE CHAIRMAN ZANZONICO: Thank you very  
5 much.

6                   MR. DAPAS: Hopefully you might want to  
7 wear it at the Commission meeting.

8                   (Laughter)

9                   MR. DAPAS: And I gladly present you with  
10 this certificate of appreciation honoring Pat D.  
11 Zanzonico PhD in recognition of eight years of service  
12 in leadership to the Advisory Committee on the medical  
13 uses of isotopes which resulted in significant  
14 contributions to the work of the U.S. Nuclear  
15 Regulatory Commission, dated March 1st, 2018, signed  
16 by Kristine L. Svinicki, Chairman of the NRC. So,  
17 congratulations.

18                   VICE CHAIRMAN ZANZONICO: Thank you very  
19 much.

20                   (Applause)

21                   MR. DAPAS: Let me present to you this  
22 certificate that's a flag of the United States of  
23 America. This is to certify that the accompanied flag  
24 was flown over the United States Capitol on February  
25 9th, 2018 at the request of the Honorable Chris Van

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1 Hollen, United States Senator. This flag was flown  
2 for Pat D. Zanzonico PhD, in honor of your retirement  
3 after eight years of federal service. So we present  
4 you with this flag and certificate.

5 VICE CHAIRMAN ZANZONICO: Thank you very  
6 much.

7 MR. DAPAS: Congratulations.

8 (Applause)

9 MR. DAPAS: Flag in front of a flag.

10 (Laughter)

11 MR. DAPAS: Thank you for the opportunity  
12 to make that presentation and look forward to hearing  
13 the remarks that you'll have with the Commission later  
14 this morning.

15 And again, I really do very much  
16 appreciate the expertise in the input that you provide  
17 because they really play an important role in  
18 determining what is the best regulatory approach going  
19 forward and how you represent the medical community  
20 and the patients' rights advocate and how important  
21 that is. So thank you for that and I hope you enjoy  
22 the rest of your meeting and we'll see you in the  
23 Commission hearing room here shortly. So thank you.

24 (Off record comments)

25 MS. WU: This is a tough act to follow so

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1 I will move on to the next topic. All right, so I'm  
2 Irene Wu, I'm with, I'm a project manager here at the  
3 NRC and I'm happy to be able to talk to you today  
4 about the Emerging Medical Technology's Commission  
5 paper.

6 I had hoped to be able to give you more  
7 information and give you a more heavier presentation  
8 than what I have in the slides for you today, but  
9 unfortunately the paper right now is still in  
10 concurrence so everything is still pre-decisional.  
11 And we are hoping that it goes to the Commission  
12 within the next few weeks.

13 But in the meantime, I'm happy to give you  
14 an overview of what the paper covers and give you a  
15 general feel of what it will hopefully be when it  
16 comes out.

17 MR. DAPAS: I just have to offer one  
18 comment. I've reviewed the paper and incorporated my  
19 comments and hopefully in the next few weeks it will  
20 go up --

21 MS. HOLIDAY: Thank you, Marc.

22 MS. WU: Thanks, Marc. Okay, so the  
23 purpose of the paper is to provide the Commission with  
24 the NRC staff's review of the emerging medical  
25 technologies program.

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1           So it is an information SECY paper. And  
2 it also serves another purpose in forming the budget  
3 formulation process here.

4           We seem to be always going through budget  
5 formulation here and working on the future, so to  
6 inform 2020 and beyond and help inform that. Again,  
7 this is a staff generated paper, it is not an SRM  
8 directive paper.

9           So general content and feel for the paper,  
10 again, this, it does provide a general process for how  
11 we review emerging medical technologies. So as you  
12 know, we get a lot of input from various stakeholders,  
13 such as yourselves, FDA, manufacturers of these  
14 technologies and Agreement States.

15           In the cases where we do our review and  
16 the medical technologies don't necessarily fall under  
17 a specific modality and we determine that it falls  
18 under a 35.1000, we'll form an NRC agreement state  
19 working group.

20           And so the paper kind of highlights that  
21 general process. It also discusses, includes a brief  
22 discussion of the past in process and anticipated  
23 future reviews of medical technologies.

24           So if you've seen the medical, the NRC  
25 medical uses licensee's tool kits, we have a list of

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1 the past reviews that we have done with links to the  
2 specific licensing guidance. The paper will also  
3 include some of the ones that are currently in  
4 process.

5 And then again, based on different input  
6 from different stakeholders, what we think we might be  
7 getting in the future years.

8 And then there will be a nonpublic  
9 enclosure that has resource estimates for the review  
10 of new technology and guidance development, and those  
11 resource estimates are based on what we've done in the  
12 past and what the resource utilization has been. And  
13 again, sort of crystal balling it, when we think the  
14 review might be coming to the NRC.

15 So, I've just listed a few examples of  
16 some past reviews that we've done. And again, this is  
17 on the NRC medical uses licensee toolkit website.

18 The first two I believe are both, both  
19 resulted in 35.1000 licensing guidance. And the last  
20 one fell under one of the individual modalities, but  
21 on the website, we did document our licensing decision  
22 through a memorandum to the regions.

23 So some examples of in-process reviews.  
24 And these were touched upon yesterday at the meeting.  
25 Yttrium-90 Microspheres, the Leksell Gamma Knife®

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1 Perfexion™ and Icon™. And then also the Lutetium-177  
2 dotatate.

3 So the first two we are working on updates  
4 to the 35.1000 licensing guidance. And the last one  
5 will likely result in a memo to the regions.

6 And then, again, these lists aren't  
7 complete of what's going to be in the paper itself,  
8 but I did want to show a few of the anticipated  
9 reviews that we see coming in FY2020, FY2023. Again,  
10 the list will be more comprehensive in the paper.

11 So those include Phosphorus-32 OncoSil  
12 miroparticles, the MASEP Infini cobalt-60 stereotactic  
13 radiosurgery and the GammaPod cobalt stereotactic  
14 radiotherapy.

15 So as I mentioned before, sort of the next  
16 steps is the paper, is going through our internal  
17 concurrence process. We hope that it gets to the  
18 Commission sooner rather than later.

19 And typically, once the paper is up to the  
20 Commission it takes about two weeks before it gets  
21 released to the public. And we can make sure that we  
22 get a copy to the ACMUI and also really, you know,  
23 send it via our medical list serve and make sure it's  
24 out there.

25 So I think that everything.

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1 CHAIRMAN ALDERSON: Comments? Dr.  
2 Zanzonico.

3 VICE CHAIRMAN ZANZONICO: How is it  
4 decided or what's the mechanism for choosing, if  
5 that's the right word, what new technologies to  
6 address in guidance or otherwise?

7 Is it just through licensee applications  
8 or is there some other mechanism for this sort of  
9 thing?

10 MS. WU: Do you want to field that?

11 MR. BOLLOCK: Yes, I can field that. This  
12 is Doug Bollock.

13 So when the NRC receives, sometimes it is  
14 through a license amendment the NRC will receive  
15 information on a new drug, a new technology,  
16 something. If it's something that hasn't been  
17 licensed before, typically the regions or sometimes  
18 the States, will contact our group.

19 And we just look, the first look is, does  
20 this drug, does this technology, fit into one of the  
21 modalities in 35.300, Sections D to L. So, is it  
22 under, can it already be licensed under 100, 200, 300,  
23 400, 600.

24 If I cannot be licensed under one of those  
25 for whatever reason, there is a part of the system,

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1       specifics of the system that are, either aren't  
2       directly addressed or it's, would not be able to meet,  
3       some specifically would not be able to meet one of  
4       those sections, then we have to, then if it falls  
5       under the 35.1000 regulation and we have to come up  
6       with the specific license conditions.

7                 And that's what we develop, we call it the  
8       licensing guidance but really it's guidance to our  
9       license reviewers with specific license conditions we  
10      deem, the NRC deems necessary for the safe use of the  
11      technology. So yes, it has to not fit in a section  
12      that's already there for us to develop the technology.

13                MS. HOWELL: Yes, so it's not so much a  
14      matter of us electing which radiopharmaceuticals  
15      treatment modalities we're going to look at or not  
16      look at, it's a matter of the various mechanisms that  
17      bring that new technology to us. And it could be an  
18      agreement state, getting an application for an SSND  
19      review, it could be through any of the professional  
20      organizations with the manufacturer coming out with a  
21      new radiopharmaceutical.

22                But if Doug's group screens it and it  
23      doesn't fit into the existing sections of Part 35,  
24      then it goes through the new licensing guidance  
25      development. Very similar to what Dr. Howe did

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1 recently with the new molytech generators.

2 MS. HOLIDAY: If I could add on to that.  
3 This is Sophie Holiday.

4 Some of the members on the Committee may  
5 recall a few years ago I gave a presentation that  
6 spoke exactly to this point about, how does NRC  
7 determine if an emerging medical technology is  
8 licensed under 35.1000, it encompasses everything that  
9 both Mr. Bollock and Ms. Howell just stated for you.  
10 And I'll be happy to send those slides back out to  
11 Committee as well.

12 CHAIRMAN ALDERSON: Are there any further  
13 questions? Yes.

14 MR. OUHIB: Yes. Is there a prerequisite  
15 regarding the FDA for instance or is that possible  
16 that it's in the process?

17 In other words, does it have to be  
18 approved first before actually NRC will look into  
19 that?

20 MR. BOLLOCK: No. However, we tend to, we  
21 don't like to get ahead of the FDA. And then if it's  
22 something the FDA is reviewing we don't share that  
23 information with the public.

24 So those few examples that we had, we've  
25 publicly received that information about things that

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1 are coming out in the future, that's why we're able to  
2 share that. But we, in our memorandum of  
3 understanding with the FDA, we do not share that  
4 proprietary information that the FDA has.

5 So we will, as with the NorthStar, that  
6 was pretty public that NorthStar was, they publicly  
7 announced that they were putting out this new  
8 technology, they came to our public meetings and said  
9 it, so we were doing it at the same time in parallel  
10 with, we were conducting our view parallel with the  
11 FDA.

12 That is typical, but, yes, we tend to lag  
13 the FDA because they can make significant changes to  
14 designs of these technologies or adjustments to the  
15 drugs that we would change, could possibly change if  
16 we have to review. And they are a lot more, typically  
17 more stringent if they do a much broader and deeper  
18 look.

19 We look at the radiation safety aspects  
20 and the licensing and inspection aspects of it. From  
21 our perspective.

22 CHAIRMAN ALDERSON: Mr. O'Hara.

23 MEMBER O'HARA: Yes. The GammaPod was  
24 recently cleared. As a matter of fact, there was a  
25 press release from the FDA because of the unique

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1 nature of the GammaPod. And we do, usually we work  
2 closely with the NRC on these issues for new devices.

3 CHAIRMAN ALDERSON: Yes, Ms. Weil.

4 MEMBER WEIL: Thank you. We won't see any  
5 of this information until it's public, is there  
6 nothing that the Members of this Committee who use  
7 these technologies could offer in the pre-decisional  
8 process while we are reviewing stuff?

9 MR. BOLLOCK: Staff actually does, on  
10 occasion, reach out to Members of the ACMUI or medical  
11 consultants as need for specific technologies in  
12 helping us review that.

13 One of the examples was, with the  
14 Germanium/Gallium generators, I know we reached out to  
15 the previous nuclear pharmacist from the ACMUI and,  
16 yes, yes, we reached out. He is a, as an ACMUI member  
17 then we kept him on as a medical consultant.

18 So we do reach out to ACMUI members in  
19 helping us review. And then of course most of these  
20 technologies, and all of the initial reviews of  
21 technology, we do share with the ACMUI and seek ACMUI  
22 input.

23 CHAIRMAN ALDERSON: Other questions or  
24 comments? Seeing none, thank you.

25 So we are well ahead of schedule. And we,

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1 our next activity listed on the agenda is a break and  
2 then the Commission meeting. So --

3 MS. HOLIDAY: Dr. Alderson, this is  
4 Sophie. If I may, as we've done in the past, when we  
5 have been significantly ahead of schedule, my  
6 suggestion is, is it possible, would the Committee  
7 entertain my doing the administrative closing portion  
8 of the meeting where we can provide some tentative  
9 dates for the fall meeting?

10 CHAIRMAN ALDERSON: Right. Unless I hear  
11 objection to that, and I see none, that's fine, you  
12 can go ahead with that.

13 MS. HOLIDAY: Okay. So, for all of the  
14 members on the Committee, I provided a meeting doodle  
15 to the membership to provide tentative dates for the  
16 fall ACMUI meeting. Again, our fall meeting occurs in  
17 either September/October.

18 I had 11 responses, and not surprising, I  
19 didn't get one set of dates where 11 people were  
20 available. However, the date that had the most  
21 promise was September 20th and 21st.

22 The only member that had indicated they  
23 were not available was Dr. Ennis. Are there other  
24 Members that are not available on September 20th and  
25 21st?

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1 CHAIRMAN ALDERSON: We're checking. I  
2 don't see anyone saying they're not available.

3 MS. HOLIDAY: Okay. So I would like to  
4 propose that we set September 20th and 21st as our  
5 first option for the fall meeting. So now we'll have  
6 to pick our backup dates.

7 Interestingly enough, I have three sets of  
8 dates where nine out of 11 responded were available.  
9 However, of the three sets of dates, our new ACMUI  
10 Chairman will not be available for two of those  
11 meeting dates.

12 But the third date where he is available,  
13 our current presiding ACMUI Chairman, Dr. Alderson, is  
14 not available. And his, the person who we have  
15 selected, Dr. Schleipman, to take on the new Health  
16 Care Administrator position, assuming that he has  
17 received his clearance and was able to be a full  
18 voting member, is also not available.

19 So I'll just throw out the three sets of  
20 dates. The first set is September 17th and 18th.  
21 Both Dr. Ennis and Dr. Palestro indicated that they  
22 were not available.

23 Then there is October 4th and 5th, again  
24 Dr. Ennis and Dr. Palestro are not available. And  
25 then the last set is October 10th and 11th where both

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1 Dr. Alderson and Dr. Schleipman are not available.

2 So, I will now leave this most important  
3 backup date decision to the Committee for discussion.

4 (Off microphone comment)

5 MS. HOLIDAY: Yes, ma'am. The first set  
6 of dates for alternative, they're tentative second  
7 choice, is September 17th and 18th, the second set is  
8 October 4th and 5th and the last is October 10th and  
9 11th.

10 MEMBER ENNIS: I can do October 4th and  
11 5th. Though I had indicated --

12 MS. HOLIDAY: Okay.

13 CHAIRMAN ALDERSON: Microphone.

14 MEMBER ENNIS: Oh, sorry. I could do  
15 October 4th and 5th, so if I indicated otherwise  
16 that's not correct.

17 MS. HOLIDAY: Okay.

18 MR. GREEN: Sophie, with the change of  
19 folks in certain roles and certain people unable to  
20 attend, are you having a problem getting a quorum?

21 MS. HOLIDAY: I'm not having a problem  
22 getting a quorum because as you know, for a quorum we  
23 have to have, sense there are only ten current voting  
24 members, to have a quorum I need to have six. And  
25 this wouldn't impact the six, there are just

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1 considerations that, you know, for one, do we mind  
2 having our new chairman not present for the meeting,  
3 in which case the Vice Chairman can still preside as  
4 acting Chairman --

5 (Off microphone comment)

6 (Laughter)

7 MS. HOLIDAY: I understand. The other  
8 consideration would be, if this will be Dr. Alderson's  
9 last meeting, like I said, assuming that Dr.  
10 Schleipman is able to obtain his security clearance,  
11 we would not be able to do out proper special fair  
12 well presentation to Dr. Alderson. Yes, Dr. Ennis.

13 MEMBER ENNIS: Well it seems pretty clear  
14 we should do the date that I'm the only one who cannot  
15 attend since I'm less vital than the people going off.

16 I may be able to make it, it's in my holiday season,  
17 as you can kind of see from the schedule.

18 MS. HOLIDAY: Yes.

19 MEMBER ENNIS: And even though those are  
20 not actual holiday days, I still have personal stuff  
21 that needs to kind of get done that I may not be able  
22 to do if I were to come to the meeting, so I will  
23 figure out whether I can come for part or all the  
24 meeting or not. But if I am the only one and the  
25 chairs and vice chairs are all available on those

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1 dates, it's pretty clear that we should stick with  
2 that date.

3 MS. HOLIDAY: Okay.

4 MEMBER PALESTRO: So, excuse me?

5 MS. HOLIDAY: Yes.

6 MEMBER PALESTRO: I don't remember the  
7 poll at this point, there is nothing --

8 CHAIRMAN ALDERSON: Microphone please.

9 MEMBER PALESTRO: Yes, this is Dr.  
10 Palestro. I don't remember the poll at this point but  
11 there was nothing after the middle of October? Okay.

12 MS. HOLIDAY: There is not. So as you can  
13 see on our calendar here, the ASTRO Meeting takes  
14 places October 22nd through 24th then several of the  
15 members, we wouldn't have a quorum for the remaining  
16 dates on the month.

17 MEMBER PALESTRO: And the best of these  
18 three dates, for second choice for me, would be 9/17  
19 and 18. If that's what it comes down to, I'll just  
20 rearrange my schedule.

21 MS. HOLIDAY: Okay.

22 MEMBER ENNIS: So, 9/18 is a definite,  
23 that's really not, I can probably come for the  
24 Thursday the 20th. If we do the 20th and the 21st I  
25 could probably, I could be here for the 20th. I don't

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1 think I can stay for the 21st except maybe a very  
2 short time in the morning.

3 MS. HOLIDAY: Okay. So I think September  
4 20th and 21st still remains the Committee's first  
5 choice, but so for the second choice it sounds like  
6 our second choice will be September 17th and 18th.  
7 We'd still be in the same boat in terms of not having  
8 Dr. Ennis.

9 Also remembering that our fall meeting is  
10 when your subcommittee does their medical events  
11 presentation, so that means he may delegate that to  
12 anyone of you lucky members on the Committee.

13 So, I guess at this time I'd like to  
14 confirm with the Committee. Our first choice for the  
15 fall meeting will be September 20th and 21st and our  
16 second choice will be September 17th and 18th. Is  
17 there a consensus amongst the Committee Members?

18 CHAIRMAN ALDERSON: It seems as if there  
19 is, no one is objecting.

20 MS. HOLIDAY: Great. Thank you very much.

21 CHAIRMAN ALDERSON: All right, is there  
22 anything else we can bring forward?

23 MS. HOLIDAY: I do not believe so.

24 (Off record comments)

25 MS. HOLIDAY: After, since the Commission

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1 meeting doesn't start until 10 o'clock, we were going  
2 to take a break at 9:30 because that would give the  
3 Committee enough time to travel to the commission  
4 hearing and get settled.

5 After the Commission meeting concludes, of  
6 course there is the group photo with the Committee  
7 Members and the Commission, we break for lunch.

8 And when we come back from lunch, the only  
9 items on the agenda are Dr. Zanzonico's fair well  
10 remarks, open forum and then the administrative  
11 closing portion where I go over any new  
12 recommendations or actions that have occurred during  
13 the course of this two day meeting.

14 So we have 23 minutes before the 9:30  
15 meeting, the Committee may either take a much longer  
16 extended break or if Dr. Zanzonico would like to make  
17 his remarks.

18 VICE CHAIRMAN ZANZONICO: I'm happy to do  
19 that.

20 MS. HOLIDAY: If you think you can do that  
21 in 23 minutes.

22 VICE CHAIRMAN ZANZONICO: I think so.

23 (Laughter)

24 VICE CHAIRMAN ZANZONICO: Usually it takes  
25 me longer than that to say hello, but --

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1 (Laughter)

2 VICE CHAIRMAN ZANZONICO: -- I can make an  
3 exception in this case.

4 MS. HOLIDAY: Okay, very well.

5 VICE CHAIRMAN ZANZONICO: Well, thank you  
6 all again. It's hard to believe it's been eight  
7 years. And a lot has happened, I'm sure, to all of us  
8 in that time.

9 We've had our first grandchild and we're  
10 expecting our second. And a lot of other good things  
11 have happened.

12 And there are a few technical sort of  
13 institutional observations, suggestions, comments I  
14 wanted to offer. And I wish I could say they were  
15 particular insightful or novel, but none of them are.

16 But I'll say them nonetheless.

17 I think the first and foremost, having had  
18 very little interaction with regulators at this level,  
19 in this depth prior to my membership on the ACMUI is  
20 how enormously impressed I am with the NRC staff and  
21 with its dedication to its mission and their technical  
22 expertise.

23 I know it comes as a shock to many people  
24 in the room that many licensees and end users actually  
25 think there's an adversarial relationship between

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1 regulators and end users. And when you work with the  
2 NRC staff firsthand, there's no basis for that at all.

3 I mean, it really it is a very supportive attitude to  
4 advance and do all they can to not impede in any way  
5 clinical care and advancement of medical science and  
6 so forth.

7 And somehow the NRC needs to do a better  
8 job of getting that message out that they really are a  
9 facilitatory of medical practice of advancements in  
10 medical care and so forth and not purely a regulator.

11 Certainly, that's their primary mission.  
12 It's a necessary mission and so forth. But they need  
13 to do a better job of putting a positive spin, a  
14 justifiable positive spin on all they do and all they  
15 have to offer.

16 And sort of a corollary of that is, given  
17 the technical expertise, the very impressive technical  
18 expertise available on the NRC staff, is making that  
19 technical expertise in some way available to end  
20 users. Especially end users that may be under-  
21 resourced.

22 And somehow I think the NRC should be more  
23 proactive in somehow being a collaborator with  
24 licensees and not simply, and we've heard this before,  
25 not simply a reactive body. But again, I've been so

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1 impressed with the technical knowledge, technical  
2 expertise of really everyone on the staff.

3 And it just seems that there is so much  
4 benefit to be gained from that by sharing that  
5 expertise with the end user community, with the  
6 licensee community.

7 The other point, and it actually segues  
8 into the last presentation, on the other hand, is that  
9 somehow the flexibility and the adaptability of the  
10 NRC needs to be expanded, needs to be improved.

11 We saw this firsthand, the ACMUI has seen  
12 this firsthand, with Xofigo and Radium-2223  
13 Dichloride. Which at the time was a completely new  
14 class of radiopharmaceuticals.

15 And it generated, understandably, a lot of  
16 angst among the NRC and the regulator community. And  
17 I think fortunately for all of us, that's just the tip  
18 of the iceberg, I mean there's going to be advances in  
19 theragnostics use of diagnostic therapeutic pairs for  
20 personalized treatment of cancer and other diseases.

21 There's going to be increased use of  
22 multimodality therapy. Johns Hopkins, for example, is  
23 using radioiodine therapy in conjunction with external  
24 beam radioiodine to target metastatic thyroid cancer.

25 And those sorts of combination therapies,

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1 radiation based combination therapies are likely to  
2 increase. There is certainly going to be an increase  
3 in alpha particle radiation therapy.

4 We have at Memorial, trials planned with  
5 pre-targeted radiotherapy using alpha particle  
6 emitters and there's been very impressive reports from  
7 Europe using PSMA targeted radioligand labeled with  
8 alpha particle emitters. And the improvement in  
9 therapeutic response with those versus Lutetium-177  
10 labeled versions, you know, bank under miraculous.

11 At Memorial, we're increasingly using  
12 regionally administered radionuclide therapy. For  
13 example, children who have leptomeningeal disease and  
14 are treated with an I-131 labeled antibody HH9, had a  
15 five year survival of under ten percent. Now, those  
16 same kids, after long-term follow-up, have survivals  
17 of well over 90 percent.

18 And, again, leading to the alpha particle  
19 radiotherapies, I think it was fortuitous that the  
20 first of these was radium-223. Which among the  
21 transuranics has a relative simple, a very simple in  
22 fact, decay scheme. It decays to a stable daughter.

23 Most of the transuranics and most of the  
24 alpha particle emitters that are being developed for  
25 radionuclide therapy have much more complex decay

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1 schemes with multiple daughters and their own  
2 particular bio-distributions and so forth. And those  
3 are going to present special problems.

4 The point being, there's a lot on the  
5 horizon. Very new, very different applications of  
6 radionuclides. And we've all seen, pretty  
7 diplomatically, the very deliberate pace of  
8 rulemaking.

9 And so there needs to be a more flexible,  
10 a more adaptable approach to dealing with these  
11 developments, other than rulemaking. Whether that  
12 lies in guidance or some other mechanism.

13 These things are coming down the pike and  
14 they're going to come down the pike at an accelerated  
15 pace. And somehow, so as not to impede their clinical  
16 implementation, there seems to be a need for an  
17 accelerated pace of addressing them among the  
18 regulators.

19 Another point is, I think the NRC, and in  
20 turn agreement states, should leverage, to a far  
21 greater extent than it does, available expertise  
22 that's out there. And I'm thinking specifically of  
23 documents and other resources from the ICRU, from the  
24 ICRP. And in particular, the NCRP.

25 I think a lot of the issues that the NRC

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1 wrestles with often, have been addressed in detail, in  
2 various NCRP reports where they develop very  
3 prescriptive guidance, model procedures and so forth.

4 And I think it would circle the NRC and the user  
5 community very well, to leverage that to a greater  
6 extent than they have.

7 So, those are just some kind of technical  
8 observations I had. But more importantly, I wanted to  
9 speak to sort of the personal level of things.

10 This has been a great experience. This  
11 has been one of the greatest professional experiences  
12 in my life serving on the ACMUI. I've made lifelong  
13 friends among current and past members of the  
14 committee and the NRC staff.

15 And several people have approached me  
16 about whether this is something worthwhile to do. And  
17 I have to say, when I first joined the ACMUI, said,  
18 well, this is a nice thing to put on your resume and  
19 this will be nice to go to a meeting or two a year and  
20 just forget about it otherwise. It's a lot of work.  
21 It is an enormous amount of work.

22 But it's a very gratifying work in the  
23 sense that I genuinely feel that we have an impact on  
24 NRC decisions and on regulations and on guidance. And  
25 in that sense, it's absolutely worthwhile and I

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1 recommend it very highly to whoever may be considered  
2 for this position.

3 And I think given our locations, it's very  
4 appropriate to make an analogy. Someone once asked,  
5 well, would you rather be a Senator or a Congressman,  
6 and they said, well, I'd rather be a Senator because  
7 I'd rather be one out of 100 than one out of 400.

8 Well, here we're one out of 13, so this is  
9 even a more select group and a very responsible group.

10 So it really has been a pleasure and an honor to  
11 serve. I thank you all and I'll miss you all and God  
12 speed.

13 (Applause)

14 CHAIRMAN ALDERSON: So, Sophie, just to  
15 let other people sort of plan their day, as you look  
16 at, we've really gone through the key things for the  
17 afternoon sessions. We've determined the priorities  
18 for meeting dates in the fall, we've heard from  
19 Dr. Zanzonico, and so one wonders whether in fact  
20 Members should really be planning to leave and that  
21 will we really need to have an afternoon session?

22 MS. HOLIDAY: There is one presentation  
23 that I told you about before that Lisa Dimmick, who is  
24 our medical radiation safety team leader, wanted to  
25 give a presentation to the ACMUI very briefly during

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1 the open forum session. She wanted to be able to  
2 inform the Committee and other meetings about NRCs  
3 transformation innovation initiative.

4 It will only take about five to seven  
5 minutes but your afternoon will essentially be very  
6 short. And I, again, also need to go over any new  
7 recommendations or actions that have occurred. But  
8 essentially, I envision that we will be done very much  
9 so before 2 o'clock.

10 CHAIRMAN ALDERSON: Yes, before 2 o'clock.

11 All right, so for anyone who needed that information  
12 there you go. So, the afternoon session will conclude  
13 probably within a matter of half an hour and it will  
14 be done by or before 2 o'clock. So if that makes any  
15 difference to people.

16 Okay, are there any other issues to be  
17 brought up? We're about ten minutes ahead of our  
18 typical break but we'll break and it will be time to  
19 sort of go over your notes for the Commission meeting  
20 and to get on downstairs.

21 MS. HOLIDAY: Unless any other Member  
22 would like to make any remarks for Dr. Zanzonico? I  
23 saw looks on faces.

24 CHAIRMAN ALDERSON: Okay.

25 MR. OUHIB: Yes, Dr. Zanzonico, your words

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1 were very moving for us non, not clear yet, but scary  
2 at the same time.

3 (Laughter)

4 MR. OUHIB: No, just kidding. I think you  
5 put it very well. If I might add one item to the NRC  
6 is really to provide, I know the ACMUI is going to be  
7 reaching out to, have been, reaching out through  
8 organization, been at meetings and so on and so forth.

9 I really like to see more support from the  
10 NRC having NRC staff available at national meetings.  
11 It is very, very useful. Because that's where things  
12 will change.

13 It's the face-to-face interaction. And to  
14 be comfortable, I remember a few years ago, very well,  
15 whether it's a state or NRC, then whether it's a  
16 speaker saying, I don't have we have an NRC  
17 representative in this crowd here or a State, you  
18 know, and so on and so forth.

19 But I think the more we have that  
20 interaction, and I have seen it, the better people  
21 feel comfortable discussing, reaching out and getting  
22 clarification and not have that oppose or adversary or  
23 whatever, however you want to define it, relationship.

24 And I think that's how we can make a major  
25 improvement.

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1 CHAIRMAN ALDERSON: Okay. Dr. Metter.

2 MEMBER METTER: Yes, thank you. Well, it  
3 was about a year and a half ago I believe, Dr.  
4 Alderson had put on a request that we go to our  
5 individual societies and do just that. And it's a  
6 session we call speak to the regulators, which I've  
7 done with the ACR. And Dr. Palestro and I have done  
8 that at SNMMI.

9 And actually, it's going to be probably a  
10 regular session at our annual society meeting. And  
11 it's been very well received.

12 And Doug's been there and Said's been  
13 there and it's been very helpful. They've done a lot  
14 of questions and it's very well received. And so I  
15 think that has already taken place, at least in the  
16 societies I've been involved with.

17 I also would like to thank Dr. Zanzonico.

18 You know, when you first are on this Committee and  
19 you're made in charge of a Subcommittee, thank you to  
20 Sophie, you get really nervous, but Sophie goes, it's  
21 always the favor thing, but we'll help you.

22 (Laughter)

23 MEMBER METTER: But when Pat's on the  
24 Committee I feel really, very assured. Your expertise  
25 has been invaluable and thank you so much.

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1           And I know you work very, very hard but  
2 your expertise is very well, very valuable to me and  
3 to the Committee. And thank you so much for all your  
4 work.

5           CHAIRMAN ALDERSON: I think one thing that  
6 I've heard several people say, and I really do believe  
7 myself that it's true, this is a particularly good  
8 group and the groups that have overlapped over these  
9 last several years, on this group of 12 or 13, have  
10 really been very high-quality people with great  
11 expertise, very easy to work with.

12           And Pat has been one of the people whose  
13 exemplified that. And it's made working on the  
14 Committee a real pleasure, so, Pat, we thank you for  
15 that.

16           Are there any other comments that people  
17 would like to make? Yes, Mr. Green.

18           MR. GREEN: This is a two-headed question.  
19 It's a question for the NRC and it's a question for  
20 the professional societies.

21           I think the outreach has been great. I  
22 attended the presentation at the SNMMI last year that  
23 Dr. Palestro had spoke at and Dr. Metter.

24           I was wondering if the professional  
25 societies at their annual meetings, SNMMI or ASTRO or

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1 whatever, if they can make available one of those, on  
2 the Exhibition Hall floor you've got the small little  
3 booths that are typically rented by commercial firms  
4 with a table and a drape, if they can make available,  
5 or willing to make available, for the NRC to have an  
6 NRC member of staff. Folks can come through that  
7 Exhibit Hall and talk face-to-face with the mysterious  
8 regulator that, you know, I think it would be great.

9 So it would take two part, the willingness  
10 of the NRC to have someone in attendance and a place  
11 for them to call home for that day or two in the  
12 Exhibition Hall.

13 MR. BOLLOCK: And I can speak to a little  
14 bit of that. We have, on a couple of occasions, APM  
15 in particular has given us a booth a couple of years  
16 ago. They, I believe they gave it to us essentially  
17 for free, and it was in D.C. so we had a lot of, you  
18 know, no travel costs for us so we had multiple staff  
19 members there the entire two or three days. So that  
20 was very good.

21 We've also, so we have rented out a booth,  
22 I believe also at AAPM, two years prior to that. A  
23 year or two prior to that. It had a poster to discuss  
24 the draft rule for Part 35. So we have found success  
25 with that.

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1           And when Dr. Alderson started this  
2 initiative to increase the communication with the  
3 professional societies and the Panel for discussions,  
4 we've worked very hard, staff and NRC management, to  
5 prioritize the travel so that we can ascend at least  
6 one of the staff to each of the major society  
7 meetings. And we continue to do that.

8           As I, I think about two years ago I spoke  
9 about our, we do have budget constraints. Our travel  
10 budget is very small for the group that we have. I  
11 mean, extremely small.

12           But, we've been successful, I believe in  
13 the past two years, of getting at least one  
14 representative at each of the meetings. And we will  
15 continue to strive for that.

16           If there are any meetings that we are not  
17 attending and you think would be worthwhile for us to  
18 attend, continue to share that information with myself  
19 or any of my staff and we will strive to do so.

20           But, you know, so there is the balance.  
21 We have limited, very limited resources, especially  
22 with travel. We've found ways to maximize, we have  
23 found ways to maximize our participation and really  
24 have these meetings higher priorities, as high as  
25 priority as we can.

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1           Because it's not just my group, it's the  
2           division's travel budgets so I have, there are other  
3           branches that are competing, right, for the little bit  
4           of travel money. But we --

5           MS. HOWELL: We do have --

6           MR. BOLLOCK: -- have been successful.

7           MS. HOWELL: We do have the capacity to  
8           have some of the senior regional staff members also  
9           participate in meetings, depending on their location,  
10          since we know they vary around the country. So, I  
11          think the important message is to make sure that Doug  
12          and his team are informed of meetings that you think  
13          would benefit from our presence.

14          It's a win, win. The community that we  
15          regulate gets to see us perhaps in a different  
16          environment, in a different light. And we have the  
17          opportunity to gather more information that is  
18          currently meaningful to us in our regulatory  
19          perspective.

20          MR. BOLLOCK: Yes. And we have even, we  
21          tried. We think outside the box sometimes and if  
22          there is a meeting in California that we can't make, I  
23          know I've called into an SNMMI government affairs  
24          meeting to have a good discussion with them and talk  
25          about some of the topics of interest to us and answer

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1 questions.

2 So we are willing and able to reach out in  
3 any way we can and we do strive and prioritize it.

4 And as Linda said, we also have a regional  
5 staff who for their training development and outreach  
6 they go out to a lot of these meetings as well. So if  
7 we're made aware we can coordinate with those staff  
8 and they can represent us, they represent the NRC and  
9 they can pass the information to my team as well.

10 And likewise, we share the, you know, we  
11 like to share the information that we learned with our  
12 counterparts in the regions.

13 CHAIRMAN ALDERSON: Ms. Weil.

14 MEMBER WEIL: In addition to professional  
15 societies, you've sent staff, and even a commissioner  
16 has gone to patient community meetings. The Thyroid  
17 Cancer Survivor's Association for several years had  
18 NRC staff attend and talk.

19 MS. HOLIDAY: There are two people.

20 CHAIRMAN ALDERSON: Excellent. Yes. Yes,  
21 hi, coming from the audience here.

22 MS. MARTIN: Oh, this audience likes to  
23 participate. For those that don't know me, I am  
24 Melissa Martin, I just finished being president of the  
25 AAPM. So, currently I guess I'm speaking as Chairman

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1 of the Board of the AAPM.

2 But, the other thing I was just going to  
3 reach out to you is, we start planning our AAPM  
4 meetings literally one year in advance. We would love  
5 to have a commitment from the NRC that you would  
6 provide us a speaker because we can make a designated  
7 time slot if we know in advance that we can have a  
8 speaker. It's just we can't commit a slot, two months  
9 up before the program because our program is literally  
10 set at least from October before the next meeting in  
11 July or August.

12 But we would definitely welcome the  
13 opportunity to have a designated regulator session  
14 meet with the regulator, have presentations. And we  
15 could include a state or an OAS or NRC.

16 But if we can get a, basically an  
17 agreement that the NRC would provide us a speaker, I  
18 guarantee you the medical physicist would love the  
19 opportunity to make that a designated slot in our  
20 program each year.

21 CHAIRMAN ALDERSON: So when is your next  
22 meeting?

23 MS. MARTIN: The fourth week of July.

24 CHAIRMAN ALDERSON: July.

25 MS. MARTIN: Of this year. It's always

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1 basically the last week of July, first week of August.

2 CHAIRMAN ALDERSON: So you'd be thinking  
3 now about having speakers for the meeting in July of  
4 '19 or --

5 MS. MARTIN: Correct. Because this year's  
6 meeting is set.

7 CHAIRMAN ALDERSON: Well, I think that our  
8 physics people on this Committee and the NRC should  
9 work on that and see if you can make a guarantee that  
10 will allow them to do that.

11 MR. BOLLOCK: Yes. So we are aware of the  
12 meeting every July and so far we've been sending  
13 actually two of my staff, Maryann or Katie. One or  
14 both have attended the past few years and we continue  
15 to strive for that.

16 Unfortunately, because our budget just  
17 changed year to year and then when we can get  
18 approvals for figuring out all the travel for not just  
19 our group, the larger division as a whole, I don't  
20 know that we can, unfortunately we can't make that  
21 committee.

22 CHAIRMAN ALDERSON: All right.

23 MR. BOLLOCK: But I can't say that we can  
24 --

25 CHAIRMAN ALDERSON: Well, our members

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1 should keep that in mind too.

2 MR. BOLLOCK: Right.

3 CHAIRMAN ALDERSON: And Sophie reminds me  
4 that we do need to wrap it up here this morning  
5 because --

6 MS. MARTIN: Thank you.

7 CHAIRMAN ALDERSON: Thank you very much  
8 for your comment.

9 MS. MARTIN: Yes.

10 CHAIRMAN ALDERSON: Because we do need to  
11 get down to the Commission meeting.

12 MS. HOLIDAY: One more, very quickly.

13 CHAIRMAN ALDERSON: If this happens to be  
14 a very brief comment.

15 MS. KUBLER: Sure. Hi, Caitlin Kubler  
16 with the Society of Nuclear Medicine Molecular  
17 Imaging. Our meeting is in Philadelphia this year,  
18 hopefully that means it's a little bit easier.

19 I know Doctors Palestro and Metter had a  
20 lot of questions last year after their session. So,  
21 on behalf of SNMMI we would welcome the opportunity to  
22 field questions.

23 We can advertise that on our website. We  
24 are available and we would very much like to work with  
25 the NRC to have that available.

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1 CHAIRMAN ALDERSON: Thank you very much.

2 MR. BOLLOCK: Thank you.

3 CHAIRMAN ALDERSON: All right, I think  
4 that will bring the morning session to an end and  
5 we'll prepare now to meet with the Commission. Thanks  
6 very much.

7 (Whereupon, the above-entitled matter went  
8 off the record at 9:31 a.m. and resumed at 1:33 p.m.)

9 MEMBER ZANZONICO: Okay. So welcome back  
10 everyone.

11 So, since Dr. Alderson has left to return  
12 home, as my last official act on Committee, I'll be  
13 moderating today's session.

14 And it's an open forum but it's going to  
15 begin with a presentation by Lisa Dimmick on the need  
16 for innovation and transformation. I think something  
17 we can all agree on. So, Ms. Dimmick, it's all yours.

18 MS. DIMMICK: Thank you. Good afternoon,  
19 everyone. So, I am here today in my typical job, or  
20 my regular job at the NRC is, I'm the medical  
21 radiation safety team leader, but I am currently on a  
22 detailed assignment for three months on the NRC's  
23 transformation team. So today I wanted to tell you  
24 about this initiative here at NRC that we are in the  
25 middle of.

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1           So on January 4th the NRC Executive  
2 Director for Operations, Vic McCree, issued a memo  
3 to all NRC staff on the importance of innovation and  
4 transformation here at NRC.

5           And then on January 25th the EDO issued  
6 the tasking memo to the transformation team. And the  
7 transformation team was stood up on January 29th.

8           The team comprises 16 NRC staff members.  
9 They were tasked to produce a SECY paper within 90  
10 days of the tasking date to recommend areas of  
11 transformation for the NRC.

12           So why the need for transformation, well,  
13 industry has, industry is and industry will continue  
14 to introduce new and novel technologies that challenge  
15 our current regulatory framework. Such that this now  
16 presents an opportunity for the NRC to become more  
17 agile, efficient and effective in our regulatory  
18 approach.

19           So, in this sense, transformation, what do  
20 we mean by transformation, it's really, we're looking  
21 at fulfilling or how we might fulfill our mission in a  
22 different way under a different paradigm. So it's a  
23 shift in our approach to regulation, our regulatory  
24 approach.

25           So we were tasked to develop strategies

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1 that would enhance and sustain a transformative  
2 culture here at NRC. And also, to consider specific  
3 areas of transformation that include digital  
4 instruments and controls, accident tolerate fuels, new  
5 materials and manufacturing methods, big data and  
6 advanced reactors.

7 So while that seem might very reactor  
8 centric, because that is the, I guess the bulk of NRC,  
9 no other ideas that cross the agency are off the  
10 table. So we, as the transformation team, we've  
11 received lots of ideas from all areas of NRC. And  
12 many of them are crosscutting type of ideas that  
13 people have presented to the transformation team.

14 But regardless of the transformation that  
15 might occur, NRC's mission does not change. Our  
16 mission to protect the public health and safety says  
17 and we're not changing the mission. That was one area  
18 that was, you cannot transform the mission. That was  
19 just in our tasking memo.

20 But even though, like I said, we're  
21 looking, had specific areas that we were tasked, that  
22 were being tasked to look at for transformation, we  
23 are considering all ideas that are received.

24 So, at the moment we've basically have  
25 completed our internal and external outreach.

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1 (Off record comments)

2 MS. DIMMICK: So we have basically  
3 completed our internal and out, external and internal  
4 outreach. So internally we attended office and  
5 division level meetings to present information on the  
6 transformation team and also to solicit feedback from  
7 NRC staff.

8 We have held informational meetings with  
9 staff in these specific areas. We've interviewed  
10 staff and we've had lots of information sessions  
11 trying to get the message out to staff to provide  
12 input to the transformation team.

13 Externally we've solicited some comments  
14 from the nuclear industry, non-government  
15 organizations, public organizations, private companies  
16 and other federal agencies. Basically to benchmark  
17 and leverage best practices and see where other  
18 agencies may be undergoing the same initiatives that  
19 the NRC is undertaking so that we can share best  
20 practice or benchmark these activities as we move  
21 forward.

22 We will be presenting our information at  
23 the RIC next Tuesday afternoon. We'll be able to  
24 discuss the feedback that was received, or has been  
25 received, and the potential areas of transformation at

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1 NRC.

2 So that's basically, I just wanted to  
3 inform the group of this effort. There will be more  
4 to come as we develop the SECY paper and then the  
5 Commission votes or which direction this Commission  
6 will go based on the recommendations.

7 And as we implement the transformative  
8 ideas I'm certain ACMUI will be kept informed of any  
9 changes that NRC is making in all areas of the  
10 organization. And I think that was it.

11 So this was just a one-pager but we split  
12 it up over the slide. So I think that was kind of  
13 where they concluded. So it was more to inform and  
14 that was it for today.

15 VICE CHAIRMAN ZANZONICO: Can I, will the  
16 ACMUI have an opportunity to review the paper, the  
17 SECY paper in draft form or --

18 MS. DIMMICK: No, not on this one. This  
19 one will, it will go through its concurrence process  
20 and that's in part while we will be finalizing our  
21 ideas after the RIC.

22 And then the paper will enter the  
23 concurrence process and then go to the Commission on  
24 this one. But once it's publicly, it will become  
25 publicly available we can share the SECY paper.

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1 MEMBER ENNIS: So, in terms of outreach --  
2 I don't think you reached out to us.

3 MS. DIMMICK: Correct.

4 MEMBER ENNIS: Unless I missed it.

5 MS. DIMMICK: So it was a -- it's a tight  
6 timeline for the outreach. So there was some outreach  
7 -- and we have some limitations on external outreach  
8 that we can do with regard to a clearance. So we had  
9 to stay within our limit of external outreach in that  
10 -- in that sense. And the first public outreach, if  
11 you will, will be the RIC next week. So this meeting  
12 was before the RIC.

13 MEMBER ENNIS: What about the medical  
14 constituents?

15 (Simultaneous speaking.)

16 MS. DIMMICK: Right.

17 MEMBER ENNIS: Besides us?

18 MS. DIMMICK: That -- so, there may be  
19 additional information or outreach after, but again,  
20 given the 90-day timeline and really having to  
21 complete outreach within the first four weeks of the  
22 effort -- four to six weeks of the effort -- there  
23 wasn't an opportunity to do a public outreach in that  
24 sense.

25 VICE CHAIRMAN ZANZONICO: Other questions

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1 or comments?

2 MR. OUHIB: This is more or less sort of  
3 an internal restructuring or -

4 MS. DIMMICK: Looking at our regulatory  
5 approach -- so it's an -- it is. It's looking at how  
6 we can transform our culture. So it's a big look at  
7 our change management and our culture at NRC and how  
8 we can -- what we can implement to make the culture  
9 more transformative than what it has been in the past  
10 in that sense. And then looking at specific areas  
11 that -- where NRC has been challenged, specifically in  
12 some of the reactor areas. Like digital instruments  
13 and controls and accident-tolerant fuel.

14 MR. OUHIB: So just as a follow-up, what  
15 actually triggered this effort?

16 MS. DIMMICK: I am not certain. It could  
17 be -- I could speculate that it could be a number of  
18 interactions and engagements from the public on  
19 certain reactor areas. And looking -- identifying  
20 that this might be a good time to really look at  
21 ourselves and how we can innovate and transform.

22 MR. BOLLOCK: Yes, this is Doug Bollock.  
23 It was a -- this is absolutely an NRC-driven action.  
24 We weren't directed by Congress or, you know -- well,  
25 Congress is really the only ones that can influence

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1 the commission. But they weren't an influence at this  
2 time, however there was a lot of stakeholder, public  
3 and a little bit of congressional interest because  
4 there -- some of the things that the commission had  
5 been hearing were -- like, the digital I&C. The sort  
6 of -- the power plants, they want to change out one of  
7 their safety systems to -- from old analogue, you  
8 know, 1960's, '70's technology to 1980's, 90's  
9 technology that are newer.

10 And they had a lot of difficulty in doing  
11 that. They don't have -- the reactor side and most of  
12 our other regulations don't have a 35.1000.  
13 Essentially. So there are -- there are regulatory  
14 hurdles that they would have to overcome for -- to use  
15 new technologies in a lot of -- in a lot of cases. So  
16 this is looking at what flexibilities -- what -- how  
17 can we transform to not get in the way of innovation?

18 Just because the digital I&C systems are new and  
19 we're not used to it doesn't mean that they're not  
20 safe -- and in some cases can have advantages and be -  
21 - have, you know, higher margin of safety for -- for  
22 reactor safety and those aspects.

23 MS. DIMMICK: Thank you for pointing out  
24 the 35.1000. I should have added that given the --  
25 the group. That's correct. Other areas of the

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1 regulations don't have that type of regulation that  
2 would allow a new technology to be evaluated so that  
3 it could be licensed. Go ahead.

4 MR. GREEN: It sounds like a lot of the  
5 input that you're receiving from staff and from the  
6 group is reactor-centric. Do you -- do you know if  
7 you've received any medical-related input?

8 MS. DIMMICK: I don't know that I've --  
9 that I'm not certain of -- if we have, specifically,  
10 in that regard. We've received a lot of licensing  
11 input that cross-cuts the agency for how to be more  
12 efficient and effective with licensing. So just from  
13 all aspects of the agency.

14 VICE CHAIRMAN ZANZONICO: Any other  
15 questions or comments?

16 (No audible response.)

17 VICE CHAIRMAN ZANZONICO: Okay, hearing  
18 none -- thank you very much.

19 MS. DIMMICK: Thank you very much for the  
20 opportunity.

21 VICE CHAIRMAN ZANZONICO: So I think our  
22 next and final order of business is Sophie -- Ms.  
23 Sophie Holiday on the administrative close and follow-  
24 up of different items that were addressed from this  
25 meeting.

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1 MR. BOLLOCK: I should also explain that I  
2 do -- with the issue I want to discuss, there is a  
3 chance for open forum again at the end of the meeting.

4 So just a reminder --

5 VICE CHAIRMAN ZANZONICO: Certainly. If  
6 there's -- this action was part of this -- this  
7 presentation was part of the open forum part of the  
8 program. So if there are any other issues at all that  
9 anyone would like to bring up, now is the opportunity.

10 MR. GREEN: Just kind of as a debrief from  
11 the meeting with the Commissioners, I think they were  
12 very open to the suggestions that were made by the  
13 ACMUI and I like what I heard. I think we were given  
14 the nod to go ahead and think through the projects and  
15 develop the -- the thought processes and ways to --  
16 you know, measure competency. But I didn't hear any  
17 no's.

18 VICE CHAIRMAN ZANZONICO: Any other issues  
19 either related to the Commission briefing or  
20 otherwise? Yes.

21 MEMBER ENNIS: Rob Ennis. I guess -- I  
22 mean, along those lines. I guess the social culture,  
23 subcommittees is now in a holding pattern until we  
24 hear from the Commissioners?

25 MR. BOLLOCK: So, we --

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1           MEMBER ENNIS:    Because we've made some  
2           recommendations and staff feels like they can't do it  
3           right now, essentially -- is what I understood.  So --

4           MR. BOLLOCK:    Right, and then -- you know,  
5           one of the Commissioners was very candid in -- in his  
6           thoughts on the -- on the -- and very directly said  
7           no.  But that doesn't mean -- actually it's good that  
8           you brought that out.  There are a lot of things in  
9           looking at the -- the report and what the intent of  
10          what the ACMUI -- the ACMUI as a whole, the  
11          subcommittee and then the entire community -- in  
12          positive things to -- out of that -- out of that  
13          subcommittee report.  You know, education rather than  
14          punitive for reporting medical events.  And ways we  
15          can improve that education.

16          As we discussed yesterday morning, some  
17          things that we can -- we stack and work on, ensuring  
18          the ACMUI's perspective on, you know, what you think  
19          are the common hot topics -- I mean, we said not to  
20          use the term hot topic, but the themes, I guess would  
21          be -- could be a good -- good term.  And we can share  
22          -- you know, we can share that and pass along our  
23          medical list server.

24          So actually that's -- open up the  
25          committee, are there other ways besides -- I kind of

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1 said this yesterday, you all shot -- shot for the moon  
2 a little bit with -- with what you're saying, you  
3 know. Whole -- wholesale changes, that's kind of hard  
4 for us to do. But in the meantime, while the  
5 commission is considering what was briefed to them,  
6 you know, staff, we -- there are a lot of kind of the  
7 easy fixes or little -- only takes a little bit of our  
8 effort that may have some good ground towards, you  
9 know, the end goal which -- or one of the end goals  
10 that -- that I think we all agree on is the patient  
11 safety in the safety culture. Right? We're all --  
12 we're all safety. I think we're all aligned, both  
13 staff -- energy staff, the commission and the ACMUI,  
14 in that goal. So I think there are things that we  
15 could get out of that. So I can open that back up to  
16 -- or, I guess, some of the other staff has some other  
17 opinions.

18 DR. HOWE: I would just a like a  
19 clarification, Doug, because Chairman Svinicki --

20 COURT REPORTER: Please identify yourself.

21 DR. HOWE: This is Dr. Howe. Commissioner  
22 Svinicki -- Chairman Svinicki and Barans -- she was  
23 very careful in her wording because we only had two  
24 Commissioners.

25 MR. BOLLOCK: Right.

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1 DR. HOWE: So do we expect to get a staff  
2 requirements memorandum or anything out of this  
3 meeting? Or did she consider it more of a public  
4 meeting and therefore we would not be tasked?

5 MR. BOLLOCK: I don't think it matters if  
6 it's a public meeting or not. And -- so there is --  
7 there is always the option after this meeting if the  
8 commission decides to task the staff with -- after  
9 hearing from the committee, or the members of the  
10 committee that presented -- to task the staff with  
11 some work, either, you know, do that pilot that was  
12 proposed or something -- anywhere in between based on  
13 what -- what the commission decides amongst themselves  
14 to have the task work on. And I -- Esther, do you  
15 want add any? I saw your -

16 MS. HOUSEMAN: Yes, this is Esther  
17 Houseman. I just want to point out that Commissioner  
18 Baran and Chairman Svinicki made it clear that -- that  
19 nothing was up for vote. And their comments in the  
20 meeting did not constitute a vote on any proposals.  
21 So this is certainly not a stop, pause, put this on  
22 the shelf, don't proceed commentary from the  
23 commission. They're simply letting you know their  
24 preliminary thoughts based on the presentation before  
25 them. And I should also point out, there was -- even

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1 if they were to vote, they didn't have quorum, so they  
2 couldn't anyway. So this should not affect your --  
3 your work and consideration in moving forward with  
4 your recommendations based on the feedback that you've  
5 received from the NRC staff.

6 MS. HOLIDAY: Additionally, I would like  
7 to add -- this is Sophie -- I believe your question,  
8 Dr. Ennis, is is the subcommittee in a holding  
9 pattern? I would like to clarify that the  
10 subcommittee had a specific charge. And as a result  
11 of your charge you submitted a subcommittee report  
12 which was voted on and unanimously endorsed by the  
13 full Committee. So as such the subcommittee itself  
14 has fulfilled its objectives. Now it is NRC staff's  
15 turn to do something in response to the subcommittee's  
16 -- or, the Committee's recommendations.

17 So the subcommittee itself -- there is no  
18 active action going on. Not like Dr. Palestro's  
19 Training and Experience Subcommittee.

20 MR. BOLLOCK: I would -- thank you,  
21 Sophie. And thank you, Esther for clarifying that. I  
22 appreciate that. But -- so I just open up to any  
23 other dialogue that the committee would have on the  
24 staff. And we've -- we've said this is -- it's a lot  
25 for us to do all that. We don't think we can do

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1 everything. But like I -- I just said earlier, there  
2 are things that we can do. So maybe if you want to  
3 continue further with that dialogue over the next few  
4 minutes, we are open to that and it will help us in  
5 taking any actions.

6 VICE CHAIRMAN ZANZONICO: So, the floor is  
7 open.

8 MR. OUHIB: This is Zoubir. My impression  
9 of that, there was -- there was a lot of  
10 understanding, not necessarily agreeing or endorsing.

11 However, if there were -- there were some questions,  
12 I thought, that it's almost like could you come up  
13 with something? Or clarify? Or could provide a  
14 little more details in this or in this or in that.  
15 And I think maybe if we have access to the minutes  
16 we'll be able to actually look at that and see. You  
17 know, and I can't remember, but I think there might  
18 have been one -- for you, Dr. Palestro. And if I  
19 remember correctly -- there was almost like two items  
20 that need some follow up or some work. That was my  
21 recollection.

22 MEMBER PALESTRO: I think for the Training  
23 and Experience Subcommittee, it was pretty clear what  
24 we needed to do -- and it is to continue working  
25 closely with staff to develop a program for 35.390.

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1 MS. HOLIDAY: And just for your awareness,  
2 Zoubir, minutes from the Commission meeting will be  
3 available within 30 days -- similar to the ACMUI  
4 meeting as well. And I will be happy to share that  
5 with the committee.

6 VICE CHAIRMAN ZANZONICO: Anything  
7 further?

8 (No audible response.)

9 VICE CHAIRMAN ZANZONICO: Let me just ask  
10 you this question. You indicated with respect to  
11 safety culture, medical event reporting, there were  
12 things that staff can do.

13 MR. BOLLOCK: For instance --

14 VICE CHAIRMAN ZANZONICO: For instance.

15 MR. BOLLOCK: Well, we discussed yesterday  
16 with sharing the ACMUI's -- the ACMUI subcommittee, I  
17 think they took it -- I took it on that you would give  
18 it a -- kind of, the ACMUI's subcommittee's thoughts  
19 on any themes and events in helping the education,  
20 sharing of that information for with the -- the  
21 medical community. And then we can -- we can take  
22 that and not just put it on our website, but share it  
23 in the medical list server and share the -- I don't  
24 think Sophie's pointing out that she wrote that -- did  
25 you write that down, Sophie?

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1 MS. HOLIDAY: I did. I took it as an  
2 action item.

3 MR. BOLLOCK: So we've taken it as an  
4 action item as you -- as you can see. So we will --  
5 you know, we will -- yes, I don't know that --  
6 specifically the ACMUI's actions on the medical  
7 events. Yes, there it is. I'm reading -- sorry, I'm  
8 reading top to bottom. So we will take that on as an  
9 action, share that as best we can. Are there any  
10 other things similar to that? I know we've said we  
11 are going to take a look at our Management Directive  
12 810, which is what sets the -- our response to medical  
13 events. Right, this is what -- that determines if  
14 it's a medical event over 20 percent, we send in a  
15 reactive inspection team within five days. We are  
16 considering -- so, for that we are considering the  
17 ACMUI's comments while staff goes through. It's just  
18 -- it's a normal revision cycle, but we will take that  
19 in consideration. And, you know, I can't promise we  
20 are going to make any changes. We haven't started  
21 looking at it. But, you know, there is potential  
22 there that we can consider kind of -- perhaps consider  
23 the graded -- a more graded approach. Like I said, I  
24 can't say that we're not going to react in some way.  
25 But perhaps -- give some flexibility a little bit more

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1 thought, case-by-case, and, you know, we will at least  
2 consider all that.

3 VICE CHAIRMAN ZANZONICO: Dr. Metter, did  
4 you have a comment?

5 MEMBER METTER: I was wondering, I noticed  
6 that when the different -- shows for the  
7 subcommittees, the different individuals presented to  
8 the commissioners, there was some -- these were --  
9 these slides were sent before with the reports and all  
10 that. I was wondering if they could be sent maybe a  
11 little earlier so in case there is a little discussion  
12 -- because I think there was a little concern about  
13 some changes, perhaps, before -- from the time that  
14 they were submitted till the time that it was  
15 presented. Maybe Dr. Palestro can explain.

16 MEMBER PALESTRO: Yes, I thought the  
17 preparatory session was excellent. I think they're  
18 always very good. And just a couple things. Number  
19 one, I think that we should, to the extent that we  
20 can, incorporate questions that might be anticipated -  
21 - that you would anticipate the commission is going to  
22 ask because that's always helpful to be prepared for  
23 something like that. And I've found it useful. But I  
24 think that if given the opportunity all of us probably  
25 would have made some changes to our slides. So the

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1 question arises -- I was wondering if rather than  
2 reviewing those -- those presentations the day before  
3 meeting with the commission, if they could be reviewed  
4 sufficiently in advance either by the entire committee  
5 via telephone conference, or by the chair and vice  
6 chair? Or some -- some method of review so that we do  
7 have time to make changes.

8 MS. HOLIDAY: Sure. Well, I can tell you  
9 that NRC has a procedurally -- per procedures that are  
10 set by the Office of the Secretary, presentation  
11 slides for Commission meetings are to be submitted no  
12 later than five business days prior to Commission  
13 meeting. So these had to be submitted by last  
14 Thursday on March 1st. So with that being said, of  
15 course the preparatory session that we had yesterday  
16 afternoon, of course, is significantly past that  
17 deadline.

18 MEMBER PALESTRO: Correct.

19 MS. HOLIDAY: The only thing that I will  
20 have to double check on is -- because the preparatory  
21 session -- per fact of regulations, preparatory work  
22 sessions amongst the Committee -- that is, you are  
23 preparing for a meeting -- does not have to be noticed  
24 in the Federal Register. But if there is going to be  
25 a vote, if there is deliberation -- that is where we

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1 start getting into the infringement of not being open  
2 and transparent, which per fact of regulations means  
3 it then has to be become an open, public meeting. So  
4 we will have to be very careful about that. But I do  
5 accept the committee's feedback and let me go back and  
6 check to make sure that we won't be in violation of  
7 any privacy concerns or non-transparency or -- or the  
8 Sunshine Act.

9 MEMBER PALESTRO: Understood. I mean,  
10 certainly there were no votes yesterday. And I don't  
11 remember any preparatory sessions that we've actually  
12 held a vote. It's basically reviewing and -- and  
13 making suggestions amongst ourselves. And really what  
14 I see is it's kind of an informal way. But, if it  
15 works, that would be great. And if it doesn't, it  
16 doesn't.

17 MR. BOLLOCK: Okay, I think -- this is  
18 Doug Bollock. We will -- we will check on that. I  
19 think there's the flexibility to do that. We'll just  
20 have to -- Sophie and I just have to verify that we're  
21 not -- doing -- violating any back up the ladder that  
22 --

23 MS. HOLIDAY: Additionally that means that  
24 we would -- the Committee would have to be sure that  
25 you've prepared the presentation slides earlier so

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1 that we could have section meeting if that were to  
2 occur.

3 MR. BOLLOCK: Yes, that's the -- I was  
4 going to bring that up, the other --

5 (Simultaneous speaking.)

6 MS. HOLIDAY: There are a lot of time  
7 constraints with meeting time around, of course. So.

8 MEMBER PALESTRO: But that would be --  
9 that would be established in advance. Something that  
10 we -- we -- I imagine you could have resolved for us  
11 by the full meeting, wouldn't you say? Whatever our  
12 next commission meeting is, this is the deadline by  
13 which -- or, the initial deadline for slide  
14 submission.

15 MS. HOLIDAY: Absolutely.

16 VICE CHAIRMAN ZANZONICO: Mr. Green?

17 MR. GREEN: Yes, the question is for Mr.  
18 Bollock. You know, there -- you're asking if there's  
19 simple things that the staff can do that are not  
20 massive changes. I know there's the medical event  
21 reporting requirements, but I thought we established  
22 that it's no requirement that you published the name  
23 of the licensee on the website. Can we anonymize  
24 things within your own power that's not against any  
25 regulation?

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1 MS. HOUSEMAN: This is Esther Houseman.  
2 One requirement that we do have to keep in the back of  
3 our minds, it's a bare bones statutory requirement, is  
4 the requirement for abnormal occurrence reporting  
5 which requires that the location of the facility at  
6 which the abnormal occurrence occurs be reported to  
7 Congress. We have reported location from certain  
8 agreement states that simply say a facility in the  
9 State of New York, a facility in the State of Texas  
10 because we are respecting certain laws that they're  
11 following with respect to confidential reporting. OGC  
12 would have to advise the staff on whether they could  
13 also similarly, to some degree, anonymize the facility  
14 name and location in our reporting requirements. Just  
15 wanted to point that out that that's a bare -- a bare  
16 minimum requirement that in some way we have to  
17 identify the location of the AO --

18 (Simultaneous speaking.)

19 MR. GREEN: I think if --

20 MS. HOUSEMAN: Reports.

21 MR. GREEN: I'd love to have you research  
22 those regulations and check with -- with the folks you  
23 mentioned. If it could be just a facility in Albany,  
24 New York that doesn't name the site, I think that's  
25 going towards the less appearance of punitive and more

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1 appearance of hey, report what happens. Let's learn  
2 from other people's mistakes so we don't repeat them  
3 at our facilities.

4 MS. HOUSEMAN: And OGC can certainly  
5 advise the NRC staff on that question. And then it's  
6 within the staff's purview to decide as a policy  
7 matter whether that would be appropriate.

8 MR. BOLLOCK: Right, we can -- we can take  
9 that as an action item to look into that. It's going  
10 to take some coordination from us and the -- the other  
11 offices that actually take in all the reporting. But  
12 we will -- we can definitely look into that. It will  
13 -- it won't change the fact that -- what the licensee  
14 reports to us, they have to -- I mean, that is in the  
15 regulation what -- right -- but what, what is shared  
16 on the public website, yes, we can -- we can look into  
17 what -- what we can do with that.

18 VICE CHAIRMAN ZANZONICO: Okay, further  
19 discussion of any -- any relevant matter? Dr. Metter?

20 MEMBER METTER: I'd like perhaps, once a  
21 year -- maybe in the fall -- for the different  
22 committee members that have presented for -- like,  
23 speak to the regulator sessions and just give an  
24 update of what's happened on the -- with our different  
25 society since we are looking at our external

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1 stakeholders.

2 MS. HOLIDAY: That would be an ACMUI  
3 action. So I guess -- this is Darlene's motion.

4 MEMBER ZANZONICO: Do -- do we need a  
5 motion? So that -- the motion would be for once a  
6 year for the ACMUI membership to report on their  
7 outreach activities to professional societies?

8 MEMBER METTER: Correct. Correct.

9 VICE CHAIRMAN ZANZONICO: Okay. Well  
10 that's -- there's a motion.

11 MEMBER PALESTRO: Second.

12 VICE CHAIRMAN ZANZONICO: Okay. All in  
13 favor?

14 (Chorus of aye.)

15 VICE CHAIRMAN ZANZONICO: Okay, any nays?

16 (No audible response.)

17 VICE CHAIRMAN ZANZONICO: It's unanimously  
18 approved. Anything further?

19 (No audible response.)

20 VICE CHAIRMAN ZANZONICO: It's getting  
21 awfully echoey in here.

22 (Laughter.)

23 VICE CHAIRMAN ZANZONICO: Okay, hearing  
24 none, I think that it is Sophie's turn to go through  
25 ACMUI recommendations and action items growing out of

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1 this meeting.

2 MS. HOLIDAY: Yes, thank you. So this is  
3 the other half of the administrative closing portion  
4 of the meeting where we review any recommendations or  
5 actions that came as a result of our two-day ACMUI  
6 meeting. The first is that -- this is an NRC action -  
7 - that the NRC staff will post the full ACMUI  
8 recommendations and action charts on the ACMUI public  
9 web page. That is the charts from 2007 to present.  
10 This was as a result of the request to capture past  
11 historical committee recommendations to help future  
12 committee members as well. So I have that as an open  
13 indefinitely item.

14 Item seven -- I took after hearing the  
15 conversation yesterday that NRC staff will send out a  
16 medical list server announcement to inform their  
17 subscribers of the availability of ACMUI and NRC  
18 medical event slides each time that they are posted on  
19 the medical toolkit. The reason I took this as an  
20 action item is that there was a request or a need to  
21 better inform and educate the medical community. So  
22 each time Dr. Ennis's subcommittee completes their  
23 presentations, his slides are put onto the medical  
24 toolkit. After Donna-Beth -- Dr. Donna-Beth Howe  
25 completes her presentation they also go on the medical

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1 toolkit. However, no formal announcement is actually  
2 sent out to inform people that those slides are there.

3 We just assume people will stumble upon them. So we  
4 received the feedback that the committee provided  
5 yesterday, and this is an NRC action open  
6 indefinitely.

7 Item number eight was this morning the  
8 committee tentatively planned to hold its fall meeting  
9 on September 20th, 21st, 2018 with the backup date of  
10 September 17th and 18th. The last item, which is not  
11 on there -- which the committee just voted on -- is  
12 that the committee will have a standing presentation  
13 to be discussed at each ACMUI fall meeting for the  
14 committee members to report back on their outreach to  
15 their respective professional societal organizations.

16 Are there any questions or comments concerning these  
17 four additional recommendations and actions from this  
18 meeting?

19 VICE CHAIRMAN ZANZONICO: This is Pat  
20 Zanzonico. I have a question about number seven. I -  
21 - other than purely information, since the -- any  
22 subcommittee slides are -- are just that,  
23 recommendations which ultimately may or may not be  
24 adopted -- what's the implication or -- or purpose of  
25 doing that? In that there are many slides for many

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1 subcommittees presented at the various meetings. I  
2 presume since these are public meetings, they're all  
3 publically available.

4 MS. HOLIDAY: They are.

5 VICE CHAIRMAN ZANZONICO: So what's the  
6 special status of -- of including the any subcommittee  
7 slides in this additional posting?

8 MS. HOLIDAY: So, staff created a section  
9 on its medical use licensee toolkit probably about two  
10 -- two or three years ago to explain to any users --  
11 or any individuals that come across medical toolkit --  
12 what the purpose of the medical event reporting is.  
13 In addition, there are links to the presentations that  
14 the ACMUI has provided on their review of medical  
15 events for that, you know, particular fiscal year and  
16 NRC staff's review of the same medical events for the  
17 fiscal year. So these are just ways to inform members  
18 of the public about why NRC requires medical event  
19 reporting and here are the medical events that are  
20 reported to the NRC. And the committees reveal those  
21 events from that perspective.

22 VICE CHAIRMAN ZANZONICO: Oh, okay.

23 MS. HOLIDAY: Does that help?

24 VICE CHAIRMAN ZANZONICO: So, I was  
25 misunderstanding, I think -- and correct me if I am

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1 wrong. When you -- what's going to be posted is the  
2 medical event reporting items, not the medical event  
3 or safety culture subcommittee slides?

4 MS. HOLIDAY: No, no, no, no.

5 VICE CHAIRMAN ZANZONICO: Oh, that's what  
6 I -

7 (Simultaneous speaking.)

8 MS. HOLIDAY: I am so sorry if I -- if I  
9 was not clear.

10 (Simultaneous speaking.)

11 VICE CHAIRMAN ZANZONICO: No, that was my  
12 mistake, right.

13 MR. BOLLOCK: Right, yes.

14 MS. HOLIDAY: All of the -- all of the  
15 subcommittee reports are on the subcommittee reports  
16 web page.

17 VICE CHAIRMAN ZANZONICO: Fine.

18 MS. HOLIDAY: All of the slides for the  
19 meeting are on the meetings' web page. But those are  
20 all on ACMUI web pages. On the medical toolkit  
21 there's a link specifically for medical events.

22 VICE CHAIRMAN ZANZONICO: Understood. I  
23 misunderstood.

24 MR. BOLLOCK: Yes, we simply -- we pull  
25 out those slides specific to that presentation and put

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1 it in a -- in another spot --

2 VICE CHAIRMAN ZANZONICO: Understood.

3 MR. BOLLOCK: Like Sophie just described,  
4 yes.

5 MS. HOLIDAY: So are there any additional  
6 questions or comments on our recommendations and  
7 actions from this meeting?

8 VICE CHAIRMAN ZANZONICO: Darlene? Dr.  
9 Metter?

10 MEMBER METTER: So, I like the idea of the  
11 medical events reporting. I was wondering if there is  
12 somehow a way that you could look at, like, every five  
13 to ten years and look at the -- the spectrum? Because  
14 I think what we've seen from going through the reports  
15 that we had is that Y-90 is a huge part of this. And  
16 perhaps the make the users aware about the issues --  
17 and mainly it's, like, I look at human error, time out  
18 -- those are the major things. And maybe somehow  
19 there could be a little summary. But I don't know if  
20 you can put that on the website. Do you know what I  
21 mean?

22 MS. HOLIDAY: Do you mean a summary of -

23 MEMBER METTER: Of, like, the -- you know,  
24 issues that -- you know, 60 percent -- or, not would  
25 cause -- but, 60 percent of the medical events of the

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1 last five years have been this mainly -- a major  
2 concern would -- a major source of perhaps these  
3 events were time out -- you know, these -- attending  
4 to time out and maybe catheter. You know, certain  
5 things. You know, just maybe one or two things that  
6 maybe the user could go back and say, okay, let's be  
7 careful about this and be sure time outs are done  
8 correctly. And that everybody in the room knows  
9 what's going on. That's just -- just as an  
10 information thing for the user. And I -- I don't know  
11 if you can do that, though.

12 MS. HOLIDAY: So, NRC, we have what we  
13 call generic communications. When NRC staff  
14 identifies that there are certain trends that are  
15 happening -- such as if we, we find that there are a  
16 lot of events that are reported due to lack of time  
17 out procedure, or, you know, kinks or what -- what  
18 have you. NRC staff can issue generic communications  
19 specifically for that. I know there was one a couple  
20 years ago related to HDR and the software. So we have  
21 done stuff like that.

22 I have provided a five-year trend analysis  
23 to the committee maybe a year or so ago. And I am  
24 happy to do that going forward each year prior to Dr.  
25 Ennis's subcommittee doing their presentation.

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1 Similar to how Dr. Howe, when she does her  
2 presentation, she reiterates how many medical events  
3 were reported in the previous years. We just  
4 consolidate it into one document. Dr. Ennis?

5 MEMBER ENNIS: Yes, I think what you're  
6 looking for is what I kind of anticipate the  
7 subcommittee now doing. As -- based on our  
8 conversations yesterday, I think we're not going to  
9 recapitulate or slightly variation -- what -- what the  
10 time frame that's looking at what Donna-Beth has done,  
11 but rather actually try and do what you just alluded  
12 to, some of the themes, concepts that are repeated  
13 year after year after year. And then propose some way  
14 of getting that information out to the community.

15 CHAIR ZANZONICO: Yes?

16 MS. SHOBER: This is Megan Shober. And I  
17 think, Dr. Metter, that some of the information that  
18 you're interested in is captured already in the NMED  
19 annual reports. And those are publically available.  
20 So there's -- there are, like, historical bar graphs  
21 with different types of events, I am pretty sure. And  
22 then, for the medical events there's also like a  
23 really brief -- like, a two-sentence or three-sentence  
24 summary for a lot of those medical events.

25 MEMBER METTER: I think I like the idea,

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1           though, of including in Dr. Ennis's report because I  
2           think that's more -- I mean, we're seeing it. We're  
3           not attuned to what you're looking at. So I think the  
4           people who are involved with the audience for this  
5           actual meeting would be -- and if these slides are  
6           available on the website, then I think that they'd be  
7           more available to the people that are interested at  
8           this point in time.

9                         MR. BOLLOCK: Yes, I can talk a little bit  
10           more to what Megan was talking about. The NMED Annual  
11           Report does have that, but its' for -- I think it  
12           actually has it for all materials events. But we do  
13           break it down by category, and medical events are one  
14           them. And it will have the trends for the previous --  
15           or, for, like, five-year trends. Whether it's the --  
16           and it -- but it just -- most of those are trending  
17           numbers up and down.

18                         Also, we -- but we do look for trends in,  
19           you know, generic -- potential generic issue or -- I  
20           guess if there was repeat causes. We do look for  
21           that. And -- and like, we look at that for all  
22           materials events. But we do -- you know, part of that  
23           is -- is medical events. So we don't -- we do that on  
24           a -- on a broad scale all the time. But I think it  
25           would be helpful to us -- and I think, as a medical

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1 community, if the ACMUI has your perspective on that  
2 information. That's -- that's appreciated. I mean,  
3 we do -- staff does look at that. We do look for  
4 trends. And again, sometimes what we think is not a  
5 big deal or necessarily a trend -- that's enough for  
6 us to take a lot of action. You may think otherwise  
7 and, you know, obviously you have the experience and  
8 the clinical expertise to help inform us what should  
9 be passed along to the medical community. So we would  
10 appreciate that.

11 VICE CHAIRMAN ZANZONICO: Dr. Palestro?

12 MEMBER PALESTRO: Yes, I was just going to  
13 say that my impression from yesterday's discussions  
14 was the same as Dr. Ennis -- that the focus of the  
15 subcommittee was going to change from essentially  
16 repeating what Donna-Beth had on its cover to really  
17 more of an analysis of the data. And in terms of  
18 trends, I don't know how easy it is to access the data  
19 going back five years to identify trends, but if the  
20 subcommittee does this on a yearly basis, well five  
21 years from now we'll be able to go back -- or, you'll  
22 be able to go back and look and say this is what we've  
23 seen over the past x-number of years. And then once  
24 again, as Laura has pointed out, things that we need  
25 to have. That creates the institutional history for

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1 the future. And I really think that the subcommittee  
2 is probably the group best suited to put that together  
3 because they're part of the ACMUI and they know what  
4 all of us really are interested in seeing. And  
5 hopefully the staff will -- you know, it will benefit  
6 the staff as well. So I think that would be -- and  
7 this has come up repeatedly over the years I've been  
8 on the committee as to why have we been having  
9 essentially the same review twice a year? And I think  
10 it's a much better focus to -- to have the -- the  
11 numeric data, if you will, presented by Donna-Beth --  
12 Dr. Howe at the beginning. Or, at the spring meeting,  
13 at the fall meeting, an analysis of the data.

14 VICE CHAIRMAN ZANZONICO: Other comments,  
15 questions?

16 (No audible response.)

17 VICE CHAIRMAN ZANZONICO: Okay, hearing  
18 none, I think we are adjourned then. Thank you all  
19 and safe travels.

20 (Whereupon, the above-entitled matter went  
21 off the record at 2:15 p.m.)

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