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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

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THURSDAY,

MARCH 8, 2018

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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

NON-VOTING MEMBERS PRESENT:

RICHARD GREEN

ZOUBIR OUHIB

MEGAN SHOBER

NRC STAFF PRESENT:

MARC DAPAS, Director, Office of Nuclear Materials Safety and Safeguard (NMSS)

LINDA HOWELL, Acting Deputy Director, Division of Materials Safety, Security, States, and Tribal Programs (MSST)

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Official and ACMUI Coordinator

MARYANN AYOADE, NMSS/MSTR/MSEB

JENNIFER BISHOP, R-III/DNMS

RUSSELL CHAZELL, SECY/RAS

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

LISA DIMMICK, OEDO

SARA FORSTER, R-III/DNMS

ROBERT GALLAGHAR, R-I/DNMS

MICHELLE HAMMOND, R-IV/DNMS

LATISHCA HANSON, R-IV/DNMS

PATRICIA HOLAHAN, Ph.D., NMSS/DRM

NRC STAFF PRESENT (CONT.):

VINCENT HOLAHAN, Ph.D., NMSS/MSST
ESTHER HOUSEMAN, OGC/GCLR/RMR
DONNA-BETH HOWE, Ph.D., NMSS/MSST/MSEB
KEVIN NULL, R-III/DNMS
PATTY PELKE, R-III/DNMS
GRETCHEN RIVERA-CAPELLA, NMSS/MSST/MSEB
DIANE SIERACKI, OE/CRB
ZAHID SULAIMAN, R-III/DNMS
KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB
IRENE WU, NMSS/MSST/MSEB
SHIRLEY XU, NMSS/MSST/MSLB

MEMBERS OF THE PUBLIC PRESENT:

DAVE ADLER, American Society of Radiation Oncology (ASTRO)
ROBERT DANSEREAU, New York State Department of Health
MIGUEL DE LE GUARDIA, Cook's Children Medical Center
LYNNE FAIROBENT, *unaffiliated*
CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging
MELISSA MARTIN, American Association of Physicists in Medicine (AAPM)
RICHARD MARTIN, AAPM

MEMBERS OF THE PUBLIC PRESENT (Cont.):

MICHAEL PETERS, American College of Radiology

JOSEPHINE PICCONE, *unaffiliated*

A. ROBERT SCHLEIPMAN, Partners Healthcare

CINDY TOMLINSON, ASTRO

AGENDA

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

(8:34 a.m.)

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

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.

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.

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.

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.

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

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

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

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

And I appreciate very much the ACMUIs engagement on that important topic. The topic of considerable stakeholder interest. And thank you, Dr. Zanzonico, I hope I'm pronouncing that correctly - -

VICE CHAIRMAN ZANZONICO: That's fine.

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

Clearly you are recognized for your

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

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

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

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

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

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

licenses and program specific guidance about medical use licenses.

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

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

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

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

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

and experience requirements.

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

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

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

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

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

VICE CHAIRMAN ZANZONICO: Thank you very much.

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

(Laughter)

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

VICE CHAIRMAN ZANZONICO: Thank you very much.

(Applause)

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

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

VICE CHAIRMAN ZANZONICO: Thank you very much.

MR. DAPAS: Congratulations.

(Applause)

MR. DAPAS: Flag in front of a flag.

(Laughter)

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

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

(Off record comments)

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

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

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

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

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

MS. HOLIDAY: Thank you, Marc.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

So I think that everything.

CHAIRMAN ALDERSON: Comments? Dr. Zanzonico.

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

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

MS. WU: Do you want to field that?

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

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

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

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

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

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

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

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

recently with the new molytech generators.

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

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

CHAIRMAN ALDERSON: Are there any further questions? Yes.

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

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: Mr. O'Hara.

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

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

CHAIRMAN ALDERSON: Yes, Ms. Weil.

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

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

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

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

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

So we are well ahead of schedule. And we,

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

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

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

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

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

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

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

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

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

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

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

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

Dr. Alderson and Dr. Schleipman are not available.

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

(Off microphone comment)

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

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

MS. HOLIDAY: Okay.

CHAIRMAN ALDERSON: Microphone.

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

MS. HOLIDAY: Okay.

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

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

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

(Off microphone comment)

(Laughter)

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

MEMBER ENNIS: Well it seems pretty clear we should do the date that I'm the only one who cannot attend since I'm less vital than the people going off. I may be able to make it, it's in my holiday season, as you can kind of see from the schedule.

MS. HOLIDAY: Yes.

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

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

MS. HOLIDAY: Okay.

MEMBER PALESTRO: So, excuse me?

MS. HOLIDAY: Yes.

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

CHAIRMAN ALDERSON: Microphone please.

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

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

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

MS. HOLIDAY: Okay.

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

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

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

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

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

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

MS. HOLIDAY: Great. Thank you very much.

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

MS. HOLIDAY: I do not believe so.

(Off record comments)

MS. HOLIDAY: After, since the Commission

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

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

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

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

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

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

VICE CHAIRMAN ZANZONICO: I think so.

(Laughter)

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

(Laughter)

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

MS. HOLIDAY: Okay, very well.

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

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

And there are a few technical sort of institutional observations, suggestions, comments I wanted to offer. And I wish I could say they were particular insightful or novel, but none of them are. But I'll say them nonetheless.

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

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

regulators and end users. And when you work with the NRC staff firsthand, there's no basis for that at all. I mean, it really it is a very supportive attitude to advance and do all they can to not impede in any way clinical care and advancement of medical science and so forth.

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

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

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

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

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

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

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

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

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

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

And those sorts of combination therapies,

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

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

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

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

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

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

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

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

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

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

I think a lot of the issues that the NRC

wrestles with often, have been addressed in detail, in various NCRP reports where they develop very prescriptive guidance, model procedures and so forth. And I think it would circle the NRC and the user community very well, to leverage that to a greater extent than they have.

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

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

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

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

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

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

Well, here we're one out of 13, so this is even a more select group and a very responsible group. So it really has been a pleasure and an honor to serve. I thank you all and I'll miss you all and God speed.

(Applause)

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: Okay.

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

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

(Laughter)

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

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

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

But I think the more we have that interaction, and I have seen it, the better people feel comfortable discussing, reaching out and getting clarification and not have that oppose or adversary or whatever, however you want to define it, relationship. And I think that's how we can make a major improvement.

CHAIRMAN ALDERSON: Okay. Dr. Metter.

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

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

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

I also would like to thank Dr. Zanzonico. You know, when you first are on this Committee and you're made in charge of a Subcommittee, thank you to Sophie, you get really nervous, but Sophie goes, it's always the favor thing, but we'll help you.

(Laughter)

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

MS. HOWELL: We do have --

MR. BOLLOCK: -- have been successful.

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

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

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

questions.

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

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

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

CHAIRMAN ALDERSON: Ms. Weil.

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

MS. HOLIDAY: There are two people.

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

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

of the Board of the AAPM.

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

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

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

CHAIRMAN ALDERSON: So when is your next meeting?

MS. MARTIN: The fourth week of July.

CHAIRMAN ALDERSON: July.

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

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

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

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

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

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

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

CHAIRMAN ALDERSON: All right.

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

CHAIRMAN ALDERSON: Well, our members

should keep that in mind too.

MR. BOLLOCK: Right.

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

MS. MARTIN: Thank you.

CHAIRMAN ALDERSON: Thank you very much for your comment.

MS. MARTIN: Yes.

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

MS. HOLIDAY: One more, very quickly.

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

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

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

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

CHAIRMAN ALDERSON: Thank you very much.

MR. BOLLOCK: Thank you.

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

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

MEMBER ZANZONICO: Okay. So welcome back everyone.

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

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

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

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

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

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

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

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

So we were tasked to develop strategies

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

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

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

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

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

(Off record comments)

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

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

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

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

NRC.

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

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

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

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

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

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

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

MS. DIMMICK: Correct.

MEMBER ENNIS: Unless I missed it.

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

MEMBER ENNIS: What about the medical constituents?

(Simultaneous speaking.)

MS. DIMMICK: Right.

MEMBER ENNIS: Besides us?

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

VICE CHAIRMAN ZANZONICO: Other questions

or comments?

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

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

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

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

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

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

And they had a lot of difficulty in doing that. They don't have -- the reactor side and most of our other regulations don't have a 35.1000. Essentially. So there are -- there are regulatory hurdles that they would have to overcome for -- to use new technologies in a lot of -- in a lot of cases. So this is looking at what flexibilities -- what -- how can we transform to not get in the way of innovation? Just because the digital I&C systems are new and we're not used to it doesn't mean that they're not safe -- and in some cases can have advantages and be -- have, you know, higher margin of safety for -- for reactor safety and those aspects.

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

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

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

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

VICE CHAIRMAN ZANZONICO: Any other questions or comments?

(No audible response.)

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

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

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

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

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

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

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

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

MR. BOLLOCK: So, we --

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

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

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

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

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

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

COURT REPORTER: Please identify yourself.

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

MR. BOLLOCK: Right.

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

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

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

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

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

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

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

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

VICE CHAIRMAN ZANZONICO: So, the floor is open.

MR. OUHIB: This is Zoubir. My impression of that, there was -- there was a lot of understanding, not necessarily agreeing or endorsing. However, if there were -- there were some questions, I thought, that it's almost like could you come up with something? Or clarify? Or could provide a little more details in this or in this or in that. And I think maybe if we have access to the minutes we'll be able to actually look at that and see. You know, and I can't remember, but I think there might have been one -- for you, Dr. Palestro. And if I remember correctly -- there was almost like two items that need some follow up or some work. That was my recollection.

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

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

VICE CHAIRMAN ZANZONICO: Anything further?

(No audible response.)

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

MR. BOLLOCK: For instance --

VICE CHAIRMAN ZANZONICO: For instance.

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

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

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

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

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

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

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

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

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

MEMBER PALESTRO: Correct.

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

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

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

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

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

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

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

(Simultaneous speaking.)

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

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

MS. HOLIDAY: Absolutely.

VICE CHAIRMAN ZANZONICO: Mr. Green?

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

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

(Simultaneous speaking.)

MR. GREEN: I think if --

MS. HOUSEMAN: Reports.

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

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

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

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

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

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

stakeholders.

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

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

MEMBER METTER: Correct. Correct.

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

MEMBER PALESTRO: Second.

VICE CHAIRMAN ZANZONICO: Okay. All in favor?

(Chorus of aye.)

VICE CHAIRMAN ZANZONICO: Okay, any nays?

(No audible response.)

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

(No audible response.)

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

(Laughter.)

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

this meeting.

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

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

toolkit. However, no formal announcement is actually sent out to inform people that those slides are there. We just assume people will stumble upon them. So we received the feedback that the committee provided yesterday, and this is an NRC action open indefinitely.

Item number eight was this morning the committee tentatively planned to hold its fall meeting on September 20th, 21st, 2018 with the backup date of September 17th and 18th. The last item, which is not on there -- which the committee just voted on -- is that the committee will have a standing presentation to be discussed at each ACMUI fall meeting for the committee members to report back on their outreach to their respective professional societal organizations. Are there any questions or comments concerning these four additional recommendations and actions from this meeting?

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

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

MS. HOLIDAY: They are.

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

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

VICE CHAIRMAN ZANZONICO: Oh, okay.

MS. HOLIDAY: Does that help?

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

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

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

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

(Simultaneous speaking.)

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

(Simultaneous speaking.)

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

MR. BOLLOCK: Right, yes.

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

VICE CHAIRMAN ZANZONICO: Fine.

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

VICE CHAIRMAN ZANZONICO: Understood. I misunderstood.

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

it in a -- in another spot --

VICE CHAIRMAN ZANZONICO: Understood.

MR. BOLLOCK: Like Sophie just described, yes.

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

VICE CHAIRMAN ZANZONICO: Darlene? Dr. Metter?

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

MS. HOLIDAY: Do you mean a summary of -

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

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

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

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

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

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

CHAIR ZANZONICO: Yes?

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

MEMBER METTER: I think I like the idea,

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

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

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

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

VICE CHAIRMAN ZANZONICO: Dr. Palestro?

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

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

VICE CHAIRMAN ZANZONICO: Other comments, questions?

(No audible response.)

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

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