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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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SPRING 2016 MEETING

+ + + + +

THURSDAY,

MARCH 17, 2016

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The meeting was convened in room T-2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 1:00 p.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

FRANCIS M. COSTELLO, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

RONALD D. ENNIS, M.D., Radiation Oncologist

STEVEN R. MATTMULLER, Nuclear Pharmacist

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: ZOUBIR OUHIB

MEMBER SELECT: RICHARD GREEN

NRC STAFF PRESENT:

DANIEL COLLINS, Director, Division of Material Safety, State, Tribal and Rulemaking Programs

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Federal Officer and ACMUI Coordinator

MARYANN ABOGUNDE, NMSS/MSTR/MSEB

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

MICHAEL FULLER, NMSS/MSTR/MSEB

ESTHER R. HOUSEMAN, OGC/GCLR/RMR

DONNA-BETH HOWE, Ph.D., NMSS/MSTR/MSEB

ANTHONY C. MCMURTRAY, NMSS/MSTR/MSLB

SCOTT W. MOORE, NMSS

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEBKATIE TAPP, Ph.D., NMSS/MSTR/MSEB

MEMBERS OF THE PUBLIC PRESENT:

BETTE BLANKENSHIP, American Association of Physicists in Medicine (AAPM)

SUE BUNNING, Society of Nuclear Medicine and Molecular Imaging (SNMMI)

ROBERT DANSEREAU, New York State Department of Health

WILLIAM DAVIDSON, University of Pennsylvania

LYNNE FAIROBENT, American Association of Physicists in Medicine (AAPM)

SANDRA GABRIEL, International Atomic Energy Agency

CAITLIN KUBLER, Society of Nuclear Medicine and Molecular Imaging (SNMMI)

RICHARD MARTIN, American Association of Physicists in Medicine (AAPM)

ERIC PERRY, Kentucky Department for Public Health

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

MICHAEL SHEETZ, University of Pittsburgh

CINDY TOMLINSON, American Society for Radiation Oncology

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

(1:01 p.m.)

CHAIRMAN ALDERSON: Welcome. This is Dr. Alderson speaking. We're going to call the spring meeting of the ACMUI to order and I'm going to turn the floor over to Doug Bollock of the NRC.

MR. BOLLOCK: Thank you, Dr. Alderson.

As the Designated Federal Officer for this meeting, I am pleased to welcome you to this public meeting of the Advisory Committee on the Medical Uses of Isotopes.

My names is Doug Bollock, I am the Branch Chief of the Medical Safety and Events Assessment Branch and I have been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today as the Alternate Designated Federal Officer, Sophie Holiday, our ACMUI Coordinator.

This is an announced meeting of the Committee and is being held in accordance with the rules and regulations of the Federal Advisory Committee Act and the Nuclear Regulatory Commission.

This meeting is being transcribed by the NRC and it may also be transcribed or recorded by others.

The meeting was announced in the February

4, 2016 Edition of the Federal Register, Volume 81, Page 6056 through 6057.

The focus of the Committee is to advise the staff on issues and questions that arise in the medical use of byproduct material.

The Committee provides counsel to the staff, but does not determine or direct the actual decisions of the staff or the Commission.

The NRC solicits the views of the Committee and validates their opinions.

I request that whenever possible, we try to reach a consensus on the various issues that we'll discuss today. But, I also recognize there may be minority or dissenting opinions.

If you have such opinions, please allow them to be read into the record.

At this point, I'd like to perform a roll call of the ACMUI members participating today.

Dr. Philip Alderson?

CHAIRMAN ALDERSON: Here.

MR. BOLLOCK: Dr. Pat Zanzonico?

VIEC CHAIRMAN ZANZONICO: Here.

MR. BOLLOCK: Mr. Frank Costello?

MEMBER COSTELLO: Here.

MR. BOLLOCK: Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Dr. Ronald Ennis?

MEMBER ENNIS: Here.

MR. BOLLOCK: Dr. Sue Langhorst?

MEMBER LANGHORST: Here.

MR. BOLLOCK: Mr. Steve Mattmuller?

MEMBER MATTMULLER: Here.

MR. BOLLOCK: Dr. Darlene Metter?

MEMBER METTER: Here.

MR. BOLLOCK: Dr. Michael O'Hara?

MEMBER O'HARA: Here.

MR. BOLLOCK: Dr. Christopher Palestro?

MEMBER PALESTRO: Here.

MR. BOLLOCK: Dr. John Suh?

MEMBER SUH: Suh, Yes.

MR. BOLLOCK: Suh, sorry, Dr. Suh, I apologize.

And, Ms. Laura Weil?

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you.

I confirm that we do have a quorum.

Also at the table, we have Mr. Zoubir Ouhib. Mr. Ouhib has been selected as the ACMUI Therapy Medical Physicist and is pending screening clearance, but may participate in the meeting today. However, at this

time, he does not have voting rights.

I would also like to recognize Mr. Richard Green. He has been selected as the next ACMUI Nuclear Pharmacist but cannot sit at the table as Mr. Steve Mattmuller currently holds that position.

I would also like to add that this meeting is being webcast, so other individuals may be watching online.

We have a bridge line available and that phone number is 888-864-0940. The passcode to access the bridge line 84114 followed by the pound sign.

Individuals who would like to ask a question or make a comment regarding a specific issue the Committee has discussed should request permission to be recognized by the ACMUI Chairperson, Dr. Philip Alderson.

Dr. Alderson, at his option, may entertain comments or questions from members of the public who are participating with us today.

Comments and questions are usually addressed by the Committee near the end of the presentation after the Committee has fully discussed the topic.

We ask that one person speak at a time as this meeting is being closed captioned.

I would also like to add that handouts and agenda for this meeting are available on the NRC's public website.

At this time, I ask that everyone on the call who is not speaking to place their phones on mute. If you do not have the capability to mute your phone, please press star six to utilize the conference line mute and unmute functions.

At this point, I'd like to turn the meeting over to Mr. Dan Collins, Director of the Division of Material Safety, States, Tribal and Rulemaking Programs, for some opening remarks.

MR. COLLINS: Thank you, Doug.

I'd like to take this opportunity to welcome everyone to the spring 2016 ACMUI meeting.

As, Doug mentioned, I am the Division Director for the Division of Material Safety State Tribal and Rulemaking Programs and I replaced Josie Piccone who retired in early December.

Other organizational changes within the office of NMSS that you may be aware of is that Scott Moore is currently the Acting Office Director pending the arrival of Mr. Mark Dapas in July of this year.

And also, Joel Munday is the Acting Deputy Office Director and, when Mr. Dapas arrives, Scott Moore

will revert back to being the permanent Deputy Office Director.

So, I'll just take a moment to note that this is Mr. Mattmuller's last ACMUI meeting as the ACMUI Nuclear Pharmacist and we'd like to thank Mr. Mattmuller for your eight years of dedicated service to the staff and to the Committee.

And, tomorrow, we'll hear a special presentation from Scott Moore, as well as some farewell remarks from Mr. Mattmuller.

And with -- and, as Doug noted, with Mr. Mattmuller's departure, we have selected Mr. Richard Green as the next ACMUI Nuclear Pharmacist and we're thankful that Mr. Green could be here today.

ACMUI, just to review a couple of the more recent ACMUI activities for members of the public who may be listening, ACMUI held a teleconference on October 28th of last year to discuss the draft ACMUI Subcommittee Report on the ACMUI review and comments of three Petitions for Rulemaking.

Those were PRMs 20-28, 20-29 and 20-30 which dealt with linear no threshold model and standards for protection against radiation.

And, the Committee's report has been provided to a working group for further review and

evaluation.

Also, ACMUI held a teleconference on January 6th of this year to discuss the draft ACMUI subcommittee report on the ACMUI's review and comments on the draft final rule for Title 10 of the Code of Federal Regulations, Part 35, Medical Use of Byproduct Materials. And, the staff is diligently working to resolve comments from the Committee and from OAS at this time.

Since the summer of 2015, both the ACMUI and the staff have received numerous letters from stakeholders, patients and congressional staff members related to the training and experience requirements for authorized users for alpha, beta and gamma emitters under 10 CFR 35.390, as well as participating in briefings on Capitol Hill.

ACMUI held a teleconference last Thursday, March 10, 2016, to discuss the draft ACMUI Subcommittee report on the training and experience requirements for authorized users of alpha, beta and gamma emitters under 10 CFR 35.390.

And, as a result of that Subcommittee's hard work in addressing these issues, a new Subcommittee was formed to review and evaluate training and experience requirements across all modalities.

During the fall of 2015 ACMUI meeting, the ACMUI endorsed the draft Yttrium-90 microsphere brachytherapy 35.1000 licensing guidance. The NRC has issued Revision 9 of that guidance; that was issued on February 17th of this year.

And, later on today, you'll hear a presentation from Dr. Tapp regarding that guidance and addition areas under consideration.

Tomorrow, you'll hear a presentation from Doug Bollock regarding the OIG's audit of the NRC's oversight of medical use of nuclear material.

And also tomorrow, you'll hear from Sophie Holiday and Mr. Perry from Kentucky regarding draft licensing guidance for the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon.

And, with that, I'll turn this over to Sophie for the next item in the agenda which is a review of past ACMUI recommendations and NRC responses to those recommendations.

Thank you.

MS. HOLIDAY: Good afternoon. I hope everyone is well after having a nice lunch.

Okay, so this is a very familiar piece of our meeting. At every meeting we go over old business which is recapping all of the recommendations and

actions that were put forth by the Committee and/or staff and noting any changes.

So, a lot of what you hear today will not be much different from what you heard in October, being that for the 2007 chart, all the items that are listed as open or open and delayed are included in the current rulemaking that the Committee, as Dan said, had a teleconference this past January on.

So, we will now move on --

MEMBER LANGHORST: May I ask a question on this?

MS. HOLIDAY: Yes, ma'am.

MEMBER LANGHORST: Just for our new members, I wanted to make note of Item 3 which was approved by ACMUI on June 12, 2007. So, it predates all of us on the Committee.

''NRC staff should revise the regulation so that Board Certified individuals who were certified prior to the effective date of recognition or were certified by previous recognized Boards listed in Subpart J of the previous editions of Part 35 are grandfathered.''

I just want to let you know of that long listing recommendation.

MS. HOLIDAY: Thank you.

Okay, so we will move on to 2008. So, again, all the items in 2008 are also included in the current Part 35 rulemaking.

So, if you will go on to the 2009 chart, there's only two items and, both of these are also included in the current Part 35 rulemaking.

And so, we go on to 2011, as I've said, for the past few years, 2010 is not included because we did close all of the recommendations and actions on that chart. And, they are not, subsequently, included in the current Part 35 rulemaking.

So, then we come to 2011, and the majority of these are also included in the current Part 35 rulemaking.

I would like to call to your attention that Item Number 1 has to deal with the patient release criteria. This is pending, because, as you are aware, there are two patient release efforts going on here at the NRC, both by the Office of Research and by the Office of Nuclear Material Safety and Safeguards.

Item 6 is the indefinite open action item from the Committee to review its reporting structure on an annual basis, which you will hear from me later on this afternoon.

Item 11 has to deal with ACMUI's

endorsement of ASTRO's approach for permanent implant brachytherapy. And, this is pending, well, open but pending at the current time.

Item 13 has to deal with the written attestation which is also included in the current Part 35 rulemaking.

The same goes for Items 14 and 15.

Item 16, again, has to deal with the patient release criteria as well as Item 32.

So, this brings me to the 2012 chart. There is only one item on there. And, again, that's the same reiteration of the previous recommendation in 2011 which is to continue reviewing the Committee's reporting structure on an annual basis. So, it was reaffirmed during the 2012 meeting.

However, I will note that, while this item is listed on the 2012 chart, I would like to ask the Committee's permission to close the 2012 chart since this is a reiteration of the 2011 recommendation.

CHAIRMAN ALDERSON: You'd like to do that now?

MS. HOLIDAY: Yes.

CHAIRMAN ALDERSON: Okay.

You've heard that Sophie would like the Committee to think about or are there people who would

like to discuss that item?

Seeing no discussion, would someone like to move approval?

MEMBER LANGHORST: I'll move approval.

CHAIRMAN ALDERSON: Is there a second?

MEMBER MATTMULLER: Second.

CHAIRMAN ALDERSON: Okay. Further discussion?

All in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Opposed?

Abstentions?

Pass as unanimous.

MS. HOLIDAY: Thank you.

Okay, this brings us to 2013. As many of the members on the Committee are aware, in 2013, the ACMUI was provided with the draft proposed Part 35 rule and this is -- we spent two public teleconferences on March 5th and March 12th of 2013 receiving the Committee's comments in response to that draft proposed rule.

So, Items 1 through 13 are all included in the current Part 35 rulemaking.

Item 21 has to deal with the germanium/gallium-68 generator where the ACMUI

recommended that NRC provide regulatory relief. As we've heard from Mr. Mattmuller this morning during the Commission meeting and you will also hear from Dr. Daibes on tomorrow after -- tomorrow morning, I'm sorry, with an update on staff's efforts related to the decommissioning funding plan requirements for the germanium/gallium-68 generator.

Item 25 had to deal with the Committee's recommendation to re-establish the Rulemaking Subcommittee to review and address the staff's response to the draft proposed Part 35 rulemaking.

I would like to put forth a request to close this item since the Rulemaking Subcommittee presented its report in January of this year and the Committee endorsed that report and that is now with staff for review.

CHAIRMAN ALDERSON: All right, we'll now consider that request.

Further discussion of this item?

Seeing none, a motion to approve?

MEMBER LANGHORST: So moved.

CHAIRMAN ALDERSON: Is there a second? There is.

All in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Any opposed?

Any abstaining?

That's passed unanimously.

MS. HOLIDAY: Thank you.

MEMBER LANGHORST: May I --

CHAIRMAN ALDERSON: Yes?

MEMBER LANGHORST: Sue Langhorst.

I just wanted to point out on Item 8, again, it's that essentially gathering clause of anyone, at this point in time who is Board-Certified, so I just, again, that's our longstanding stance and recommendation to the NRC.

Thank you.

CHAIRMAN ALDERSON: So noted.

MS. HOLIDAY: Thank you.

Okay, so then we will move on to the 2014 chart.

And, the first item which is Item 6 also has to deal with the same germanium/gallium-68 topic. You'll, again, hear from Dr. Daibes tomorrow on that topic.

Items 10, 11 and 12 all have to do with the Subcommittee's report related to the Yttrium-90 microspheres brachytherapy licensing guidance.

I have noted this in red because, as this

was discussed during the October meeting, the Committee's recommendations were included in the then draft revision of that guidance which was endorsed during the October 2015 meeting.

You will hear a presentation from Dr. Katie Tapp later on this afternoon in regards to that topic.

Are there any comments, questions or concerns with my closing these three items?

CHAIRMAN ALDERSON: We'll try again. Are there items for discussion here?

Hearing none, a motion to approve the request?

MEMBER LANGHORST: So moved.

CHAIRMAN ALDERSON: And is there a second?

All those in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Opposed or abstaining?

None, thank you.

MS. HOLIDAY: Thank you.

Moving on to 2015. So, the first item on this chart is Item 7. I apologize for those of you in the back, the print is rather small, but it is available in your meeting handout.

During the March meeting, and also

reiterated during the fall 2015 meeting, the ACMUI had recommendations related to that normal occurrence criteria.

So, this item is still listed as open as we are waiting on staff's review and evaluation to revise the NRC's abnormal occurrence criteria policy statement.

Item 9 has to deal with the Subcommittee that was created to review and evaluate the 700 training experience hours related to the authorized users of alpha, beta and gamma emitters under 35.390.

I will tie this also to, and I am jumping just a bit ahead, I will tie this to the teleconference that took place just last week. So, both items are related.

So, I am requesting to close Item 9, as that Subcommittee completed their work in the October 2015 meeting related to evaluating whether or not those 700 hours was the sole contributing factor with placing hardship on the patient community.

CHAIRMAN ALDERSON: All right, same as the past few, is there further discussion on that particular item?

Seeing none, a motion to approve its closing?

There's a -- yes, there is a motion and a second.

All right, all in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Opposed or abstaining?

None.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Thank you.

MS. HOLIDAY: Item 12 and Item 13 and 14 have to deal with the Subcommittee's report and discussion about the phrase "patient intervention."

Item 14 in particular, Dr. Thomadsen previous ACMUI Chairman requested that staff provide an update during this meeting on staff's response and action to that Subcommittee report.

At this time, I would like to inform you all that, based on the prioritization of workload, including patient release and the Part 35 rulemaking, we've not been able to address the patient intervention Subcommittee report. But, we will address that as soon as staff resources are available.

CHAIRMAN ALDERSON: Thank you.

MS. HOLIDAY: Are there any questions or comments related to Item 12 through 14?

CHAIRMAN ALDERSON: There appear to be none.

MS. HOLIDAY: Great, thank you.

I'm sorry, this also includes Item 15 as well.

Okay, Item 16, again, has to deal with the training and experience for Alpha and Beta Emitters Subcommittee that presented their report on last week. So, while it's not noted open, I am also requesting to close that item as well.

CHAIRMAN ALDERSON: All right, is there discussion of this?

Just for the benefit of people who might be listening from the general public, you will hear later that we have, in fact, formed a standing Subcommittee to look at training and experience requirements across the broad spectrum, and that Committee will begin its work shortly after this meeting.

So, this is not to suggest that we are walking away from this very important issue at all.

That having been said, questions or comments about Sophie's motion to close this particular item?

Seeing none, a motion to approve?

And a second?

All in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Opposed or abstaining?

It's unanimous.

Thank you.

MS. HOLIDAY: Thank you.

Items 17 through 19 have to deal with the comments and recommendations provided by the Radioactive Seed Localization Subcommittee.

I have Item 17 as being closed because this motion did not pass. So, after this meeting, I will be closing this item from this chart.

Items 18 and 19, I have left open because my working group revising that guidance is still working on that. I am hoping that we will be able to provide the Committee with draft guidance early summertime for your 60-day review and comment period.

Okay, are there any questions related to Items 17 through 19?

CHAIRMAN ALDERSON: There are none.

MS. HOLIDAY: Great.

Item 20 is, again, when the ACMUI endorsed the Y-90 Microspheres Subcommittee report. So, I have this closed. So, I will be removing this as well.

CHAIRMAN ALDERSON: Very good.

MS. HOLIDAY: And Item 21, I am also closing because all of you are here today for the spring 2016 meeting.

Okay, item 22 has to deal with, again, the AO Criteria Subcommittee report. As I stated before, NRC staff is currently reviewing and evaluating the Subcommittee's report as well as all of the other comments that were received pertaining to the revisions of the NRC's Abnormal Occurrence Criteria Policy Statement.

So, when staff has completed its review, as was stated in the Commission meeting this morning, the Committee will receive a memorandum explaining whether or not or why we did accept and did not accept some of the Committee's recommendations.

Item 23, the ACMUI endorsed the NUREG-1556, Volume 9 Subcommittee report. I have left this item open, because, as you are aware, the NUREG-1556, Volume 9 has not been finalized yet.

And, you will also hear from Dr. Katie Tapp this afternoon regarding those efforts.

And then, the last item for 2015, a Subcommittee was created to propose the appropriate criteria for medical event reporting or events other

than permanent implant brachytherapy.

We will hear from that Subcommittee after our break this afternoon.

And now, we are into our current year, 2016. So, Items 1 through 15 all have to deal with the Subcommittee's report that had the recommendations related to the draft final rule.

Again, all of these items are open as staff is reviewing and evaluating the comments from both the Committee and the Organization of Agreement States.

Are there any comments or questions related to these items?

CHAIRMAN ALDERSON: There is, yes.

Sue Langhorst?

MEMBER LANGHORST: Yes, I just wanted to point out Item 7, that again, we're talking about grandfathering all Board-Certified individuals and on licensing guidance that that be addressed on how you deal with the various issues that current, if you don't accept that, that's how you get someone authorized.

CHAIRMAN ALDERSON: But, I think that this is a very important topic considering that we're going to be discussing in detail training and experience. So, this will almost surely come up for some reconsideration.

MS. HOLIDAY: Absolutely.

CHAIRMAN ALDERSON: Thank you, Dr. Langhorst.

MEMBER LANGHORST: Mostly for the new members, I wanted to let you know how longstanding this recommendation has been.

CHAIRMAN ALDERSON: Right, thank you.

MS. HOLIDAY: Thank you.

And then, the last item that I have that is not listed on here because it didn't quite make the print cutoff time is, again, the Committee had a teleconference last Thursday on March 10th to discuss the training and experience for authorized users of alpha, beta and gamma emitters under 10 CFR 35.390.

The Committee unanimously endorsed or approved the Subcommittee's report.

The report contained recommendations that included maintaining the current 700 hours for training and experience and also to establish a standing Subcommittee that will review the training and experience requirements across all modalities under 10 CFR Part 35.

Do you all accept my addition to the table?

CHAIRMAN ALDERSON: So, are there any additions or corrections to Ms. Holiday's report?

There is a hand from Dr. Langhorst.

MEMBER LANGHORST: Yes, on Item 13 that you have there, I found this very confusing when we were going through and I just want to suggest adding one word.

MS. HOLIDAY: Sure.

MEMBER LANGHORST: In reading it first when we were making our review, it sounded like you didn't have to send any paper in. And so, what it really means is you don't have to submit additional copies of your license application or license amendment.

So, I would just suggest that it might say submit additional copies because you have to submit something.

CHAIRMAN ALDERSON: For those who might be listening on the phone, would you just read the sentence and you would like it now to be amended.

MEMBER LANGHORST: Yes.

''The Committee endorsed the elimination of the requirement to submit additional copies of NRC Form 313, Application for a Materials License or a letter containing information required by NRC Form 313 when applying for a license, an amendment or a renewal.''

CHAIRMAN ALDERSON: Very good.

All right, so that's your proposal, that's

your motion, is there a second?

There's a second.

All right, do we wish to discuss that or does someone want to move the question?

No question, a second?

All in favor of adding this additional word say aye?

(Chorus of aye.)

CHAIRMAN ALDERSON: Opposed or abstaining?

None, it's passed unanimously.

MS. HOLIDAY: Thank you.

I will note that, while I'll make the change on this chart, these are items that were explicitly called out from the report that has been finalized, which will be included in the Commission paper as the Committee's unfettered opinions or unfettered votes.

But, members of that rulemaking working group are in this room so they are aware of your recommendation.

MEMBER LANGHORST: Thank you very much.

Sue Langhorst.

Thank you very much for that.

I just -- because this is just such a standalone thing, I thought it would be helpful to

include that word additional because it made no sense to me as an RSO.

If I'm not supposed to send in a 313 copy, how am I going to ask for an amendment?

MS. HOLIDAY: Absolutely.

MEMBER LANGHORST: So, it's just, right now, I send in my original and I have to send in a copy.

MS. HOLIDAY: Absolutely.

MEMBER LANGHORST: That's all it states. So, thank you.

MS. HOLIDAY: You're welcome.

Okay, this concludes my portion of old business. Are there any questions, comments or concerns related to?

MEMBER PALESTRO: I have one question.

So, I didn't see indicated anywhere, you know, that Dr. Alderson had, in fact, formed the Subcommittee for evaluation of training.

MS. HOLIDAY: You're correct. I have not added that yet. I was going to wait until he mentioned it during --

CHAIRMAN ALDERSON: Pat is going to mention it in a few minutes.

MS. HOLIDAY: And just leave it at --

CHAIRMAN ALDERSON: And, that was Dr.

Palestro speaking.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Any other amendments, discussion about Sophie Holiday's report?

Hearing none, Sophie, thank you very much.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Okay, so this brings us to the part of this particular session known as Open Forum.

And so, at this particular time, we will open the floor to discussions of medical topics of interest.

We'll begin with discussions among the ACMUI. It is possible, given the interest from the audience that we may, in fact, invite them to make comments after we've had sufficient time to discuss these items on our own.

And, this is the place where I will mentioned very briefly that this morning, we did meet with the Commission, the Commissioners, and we discussed -- Dr. Palestro led the discussion on training and experience issues.

We indicated to the Commissioners at that time, as Mr. Collins actually noted earlier, briefly in his comments, that we had formed a standing Subcommittee

to address training and experience requirements.

And, by standing, and we have that not ad hoc, but standing Committee, we will presume that this Committee will be functioning at each and every meeting as we go forward.

And as things may change in the medical community relating to what might be effective and appropriate training and experience for a particular issue, that Committee will already be there and will be charged with reviewing those things and bringing them to our attention and to the attention of the NRC.

So, that Subcommittee, standing Subcommittee, has been formed. Chris Palestro will be the Chair. Sue Langhorst is a member of that Committee. John Suh is a member of that Committee. Laura Weil is a member of that Committee. And, Darlene Metter is a member of that Committee.

So, I thank you very much and just wanted to make those comments to get this open session started.

So, I now will turn the floor over to members of the ACMUI who can introduce topics of interest that they may wish to discuss.

The floor is open.

Yes, Dr. Ennis?

MEMBER ENNIS: I've been hearing about

efforts of other part of the federal government who are greatly concerned about security related to the isotopes and the possible previous changes to their security requirements, eventual search requirements for a variety of aspects.

And --

CHAIRMAN ALDERSON: Yes, please start over in case the people listening from outside couldn't hear you --

MEMBER ENNIS: Absolutely.

CHAIRMAN ALDERSON: -- as you made these comments.

MEMBER ENNIS: So, I have become aware of an effort by some other branches of the federal government exploring the possibility of increasing regulation of what I call high activity radioactive sources out of a concern for terrorism.

A lot of proposals I've heard flying around and wanted to know from my colleagues whether we think that this is something that we ought to evaluate and weigh in on?

CHAIRMAN ALDERSON: All right, so, Dr. Langhorst has her hand up and she will get to comment just after I make a brief context statement.

I think that at some point in this

discussion, we might want to ask our NRC colleagues if they are aware of these issues and, if they are, they might expand upon the knowledge just to put to the table as to what might be going on.

But, Dr. Langhorst?

MEMBER LANGHORST: I have something to address there.

CHAIRMAN ALDERSON: Very good.

MEMBER LANGHORST: So, on Monday, in the Federal Register, there was an NRC Request for Comment on Part 37. That's the security regulations.

And, going through a lot questions and answers, or asking questions of licensees, in particular.

For those of you who may not know, this rule, Part 37, has been in effect since March 19, 2014 -- '15 -- '14. No, it was published then.

UNKNOWN PARTICIPANT: In '13 -- 2013, it became effective.

MEMBER LANGHORST: Right, but you didn't have to implement it until a year later, wasn't it 2014 for NRC licensees?

Agreement States had up to three years, so those Agreement States who hadn't already adopted this security requirement are due to have it in place by March

19, this week. Okay?

I looked at this and thought, do I want to suggest, because my very small Subcommittee who worked on the original Part 37, they're long gone.

But, really, the question and answer part of it, I think I would encourage licensees to submit their answers to NRC on what it means in a medical environment.

So, I just wanted you to be aware that's Federal Register, Volume 81, March 14, 2016 and it starts on Page 13263.

CHAIRMAN ALDERSON: Thank you, Dr. Langhorst.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: Given that the Agreement States are involved in this, I wonder if Mr. Frank Costello would like to make a comment?

MEMBER COSTELLO: I do.

Pennsylvania is -- I'm sorry. There we go, now you can hear me.

Pennsylvania is adopting it tomorrow, which happens to be just in time planning for us. We're one day ahead of March 19th.

I would say that, while some Agreement States adopted it early, I think most Agreement States

are adopting it just in time.

We have no running time on this. I'm just starting inspecting Part 37 this coming week for the first time.

But, I think, though, that for the most part, Part 37 does not impose, I think it only imposes administrative changes on top of what was there from the orders.

Now, there are administrative changes and there's a fair number of them, but I don't think the actual security sources are very much different than the orders.

But, there are administrative changes and I expect in the beginning to find a number of places where licensees have to fix things.

I think that's been true with the other Agreement States as well.

And, I think, having listened to NRC speak about this, I think the NRC's experience in its running time over the last few years is that, for the most part, most of the violations identified were administrative in nature.

CHAIRMAN ALDERSON: So, for those who might know exactly what that means, just could you give us one --

MEMBER COSTELLO: Yes.

CHAIRMAN ALDERSON: -- example of an administrative change that this particular requirement would lead to?

MEMBER COSTELLO: Sure.

Right now, there wasn't a requirement before to have periodic training and now, there's a requirement for periodic training.

There's a requirement for periodic audits, both of the access program or the security program itself.

There's a requirement to have a security plan and written security procedures.

These are what I think of as being administrative changes.

But, the locks and the alarms and such will be there.

Not to say there's not a fair number of those administrative changes, but I think the sources will be secured pretty much the same as they have been in the past.

And, I think the NRC, in their inspections, have been finding for the violations they've had over the last couple of years, they've largely been administrative.

CHAIRMAN ALDERSON: All right.

Would the NRC -- Dr. Langhorst has her hand up again.

MEMBER LANGHORST: I'm sorry, I wanted to make one mention about this Federal Register, the comments are due by May 13 this year. So, I just wanted to make mention of that. I forgot to do that before.

CHAIRMAN ALDERSON: Good, thank you.

Dr. Collins?

MR. COLLINS: This is Daniel Collins.

Just to provide some additional context to the Federal Register that Dr. Langhorst referenced, the NRC is required by Congress to perform an evaluation of the effectiveness of Part 37. And, that is what that Federal Register is associated with and that the NRC's report to Congress is due by the end of calendar year 2016.

So, it's looking at the effectiveness of the rule, not specifically the effectiveness of the NRC's implementation or the Agreement States' implementation of the rule.

CHAIRMAN ALDERSON: Okay.

Yes, Mr. Costello?

MEMBER COSTELLO: This is for Dan.

I mean, I know that you're here now, you

just came from Region I; can you confirm that, for the most part, the violations that the NRC's been finding for the last couple of years, I think have largely been administrative in contact nature?

MR. COLLINS: Yes, so Frank, anecdotally, what I would say is at least Region I's experience is that the vast majority of the violations we saw were things where licensees assumed that the new Part 37 was only codifying the previous increased control orders and licensees didn't fully understand that there were additional requirements in Part 37 related to training and documentation of programs such as Frank described.

So, yes, largely administrative in nature.

CHAIRMAN ALDERSON: I'll ask for one other clarification -- yes?

MR. FULLER: Well, I'd just like to mention that we've been talking the last several minutes about NRC's regulations in 10 CFR Part 37.

But, I believe Dr. Ennis's question had something to do with something totally unrelated, which is some recent initiatives and actions and meetings and so forth by other federal agencies that have to do with security of sources that might affect the medical community.

So, I would just like to point that out as

an observation so that we didn't lose track of that question.

CHAIRMAN ALDERSON: That's good, thank you.

That was Mike Fuller of the NRC.

Would someone like to give an example for our audience of one or two quotes of high activity, radioactivity sources that might be affected by this particular security regulation?

MEMBER ENNIS: So, the number one is cesium blood irradiators. So, cesium blood irradiators are the most cost-effective way to sterile blood supply, but they're a high activity sources that are considered by some to have some risk associated with that.

CHAIRMAN ALDERSON: Yes, that's good.

MEMBER ENNIS: Some of the talk that would be even to go to the point of banning that. There are alternative technologies that are more expensive. So, that would be one example.

CHAIRMAN ALDERSON: Good.

MEMBER ENNIS: Radioactive material uses for a Gamma Knife, radioactive material used for high dose rate brachytherapy are all among the isotopes that are included in the category being discussed.

And, again, regulation proposals that I've

heard include outright banning, include increasing the security requirements that would be excessively -- well, extremely expensive and might make institutions decide they couldn't afford to offer those services to have those types of equipment anymore or requirements of insurance policies, less something happen to your -- and that you would held accountable to a hospital that might make the hospital decide that that cost was too much to bear.

CHAIRMAN ALDERSON: Okay.

Dr. Langhorst?

MEMBER LANGHORST: Because I missed the last meeting of ACMUI, I sat and watched the webcast of that meeting and there was a presentation on that exact topic. I'll point you back to that presentation where groups are -- and NRC is part of that effort to look at having government licensees like I guess VA hospitals and so on look at how they can replace those types of high level sources.

So, I'd just point you back to the last meeting where that was discussed.

CHAIRMAN ALDERSON: So, we have one of the members of the public who's in the audience here who would like to speak at this time.

Please identify yourself.

MS. FAIROBENT: Thank you, Dr. Alderson.

Lynne Fairobent with the American Association of Physicists in Medicine.

And, to perhaps answer your question directly, there are a number of initiatives going on to look at this. There is currently a draft report being coordinated through the Department of Homeland Security and the National Nuclear Security Administration that has many participants on it.

The first chapter is going to address cesium chloride irradiators, not only in medical use but industrial use.

That group has been meeting for well over a year. The draft report, hopefully, will be prepared by the end of this calendar year. It has been delayed.

Secondly, Senator Carper has an amendment to the Energy Water Appropriations Bill that is very similar to the bill that was introduced last year by Senator Feinstein which the community was able to not have go forward, which directed NRC to prepare a report later that simply addressed the progress made with living under Part 37.

The language from Senator Carper's bill is very similar. It -- right now, we do not believe it's going to move. We are watching it very closely.

In fact, I have had meetings within the last three weeks with Senate Energy Committee staff and House Energy and Water Committee staff. There is a consortium of groups that are paying very close attention to this.

Some of the language that is a little troubling in Senator Carper's amendment, if it goes through, rather than saying Category I and II sources as defined consistent with the International Atomic Energy Agency's definitions leaves it to NRC to define what is Category I and Category II.

And, currently, for medical use, the only Category I and II sources are Gamma Knife, ViewRay and blood irradiators. HDR brachytherapy is not under Category II if your license condition is 20 curies or less.

And, I believe almost all licenses were amended to keep brachytherapy under the 22 curie limit which triggers it to Category II.

So, yes, there is a lot of movement. There remains extensive discussions in various places on The Hill in various committees with both individual representatives and Senate offices as well as committees of jurisdiction.

CHAIRMAN ALDERSON: Thank you for your

comment, Ms. Fairobent.

Are there other comments from members of the ACMUI or here in the audience today?

I don't know if we have anyone listening online. Is there anyone listening online that would like to discuss, make a comment on this item?

Hearing none, I believe that we have no further comments at this.

Dr. Ennis, anything final to say?

MEMBER ENNIS: Only to ask whether we think it's appropriate for us to weigh in on this and evaluate this at this time or not? And, maybe whether the NRC feels that that would be helpful or useful or not?

CHAIRMAN ALDERSON: Right, so, let's direct that question to Mr. Bollock and Mr. Collins.

The question is, is this an important issue that you believe that the ACMUI should look into and render some advice regarding?

MR. COLLINS: I think at this point I would echo the thoughts that Dr. Langhorst offered earlier that, if you have specific impacts that you're aware of on the medical community of the security regulations, we certainly want to hear from that.

So, but, I don't know that this necessarily would require you to, you know, start some separate

effort on that.

CHAIRMAN ALDERSON: All right.

Any other questions or comments on this issue?

Dr. Langhorst?

MEMBER LANGHORST: I don't have any.

CHAIRMAN ALDERSON: Oh, on another issue, Dr. Langhorst?

MEMBER LANGHORST: If we're ready to move on.

CHAIRMAN ALDERSON: I think we are ready to move on.

MEMBER LANGHORST: Okay.

I just noticed that there's no update of where we are on new Part 35. So, I just wondered --

CHAIRMAN ALDERSON: Sophie, would you comment on that, please?

MS. HOLIDAY: Yes.

As I stated during old business -- this is Sophie Holiday -- staff is currently working on reviewing and evaluating the comments received from the Committee and the Organization of Agreement States.

So, at this time, that's all I can really say. They're working very diligently to address all comments received.

So, when we're able, if something has changed, we will inform the Committee.

CHAIRMAN ALDERSON: Thanks very much.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: Any other questions or comments from people here at the meeting?

Hearing none, we'll move on to the next part of this session which is Medical Related Events. And, Dr. Howe will present the latest update on Medical Related Events.

DR. HOWE: Thank you, Dr. Alderson.

This is probably one of the most important presentations you get for the year in that it is a review of medical events that have happened over fiscal year 2015.

So this gets to -- you get a glimpse of how licensees are doing in treating patients.

First, to put things into perspective, we don't have a lot of diagnostic medical events because of the thresholds on dose.

And, each year, there are about 150,000 therapeutic procedures.

Each year, I present you with the medical events that happened in the last fiscal year, so fiscal year 2015 and I give you a perspective of what happened

in the previous year.

As you can see, there are a few more medical events in 2015. One thing that you should keep in mind is that 57 medical events is not a large number.

We are talking about -- we've got three diagnostic medical events. The diagnostic medical events are probably out of millions of diagnostic procedures.

The others are therapeutic and there are the denominator -- the cumulative denominator is probably a couple hundred thousand for that.

So, these are not large numbers.

The increases happened in diagnostic. They happened in therapeutic, unsealed material, happened in manual brachytherapy, also in the HDR Gamma Knife arena and, we actually had a few less emerging technology.

So, let's look at the diagnostic. I did this by modality, so it's a 35.200, imaging and localization.

We had three medical events. We had two technetium medical events. In both cases, the multi-dose vial was injected into the patient instead of the procedure that they were supposed to receive.

In some cases, it is because they confused

the multi-dose vial with the dose they were supposed to give. One suggestion was to use color coding. We don't encourage color coding because you put the wrong color on and you think you're safe and you're not.

And, the other is they just reach for the wrong thing and they get the multi-dose vial.

And, in each case, this is about the only time you're going to get over 5 rads whole body for diagnostic.

The next diagnostic one was sodium iodine-123. In this case, they were supposed to give 300 microcuries. They gave 3.69 millicuries and the thyroid was exposed to over 50 rad.

The physician asked for the correct dosage, but because they were going to scheduling this patient during a therapy time, the technologist ordered the wrong dosage.

They contributed it to be part of the scheduling and that they would normally have associated the numbers with diagnostic, but they didn't pick up on it because they were in therapy time slots.

So, they're going to go back and make sure all the diagnostic procedures are done in the diagnostic time slots.

Moving on to the therapeutic unsealed

material, we have eight medical events. We had one with I-124, we had six with I-123 and we had one with radium-223.

In the I-124 was a pediatric case. There was a leak at the intravenous connector. It wasn't visible because there was a lot of gauze over that area and so they didn't know that they had a leak until they had delivered only a small -- about half of the I-124 that they had expected to administer.

In I-131, I've got six medical events. In the first case, the patient had a low glomerular filtration rate score. And, the first physician ordered 509 millicuries. The second physician looked at the low score and said, I think this patient is better suited for a lesser amount of activity.

And so, both physicians ordered the material. So, the first physician ordered the 50 millicuries, the second physician ordered the 35 millicuries.

When it came time to give the administration, they picked up the wrong syringe and they gave the 50 when they were supposed to give the 35.

We had an administration of 30 millicuries instead of 3 millicuries. In that case, the written directive was incorrect. The written directive was

written for 3 millicuries but the intended dose was always 30 millicuries.

And so, no one paid attention to the written directive. And so, now there's going to be, for a corrective action, the authorized user is supposed to complete the authorization section before administration.

I'm not sure what that means because a written directive always has to be dated and signed by the authorized user before administration. Okay?

Then we gave 1.57 millicuries instead of 2 millicuries. In this case, they measured it. It was less than 20 percent, but they really weren't paying attention to the fact it was less than 20 percent and that would trigger a medical event.

So, from now on, the corrective action is to do two independent measurements and review the dose to make sure it's within 20 percent.

They delivered 142 millicuries instead of 30. It was the wrong patient. They misidentified the patient.

They administered 75 millicuries instead of 150 millicuries. And, this one, you can almost guess the reason. The dose came in two capsules, one capsule was given, the other capsule staying in the container.

And, each time I talk about an administration, this is a different licensee medical event.

The final one for the therapy is the radium-223. In this case, they delivered two dosages. But, the written directive was for only one dosage.

But, instead of reading the prescribed dose, they injected two dosages instead of the one. So, they gave essentially about 100 percent more radium-223 than they were supposed to.

So, corrective action, they're going to have technologists verify the patient information and the prescribed dosage.

Moving on to manual brachytherapy, it's not very -- we don't have manual brachytherapy generally in places outside of the prostate, but we did end up with a tunnel one this time.

In this case, they checked the patient and two and a half hours after the linens were changed, the oncologist came in and determined that one of the strands that was going through the nose was missing and they did a survey and found out the strand was in the linen.

They retrieved the stand, they put the strand back in. The patient received the dose they were

supposed to receive through the nose.

However, there could have been an exposure to the skin and they did a calculation and determined that this patient -- because it was in the bed linens, had received up to 51 rem to the skin and reported it as a medical event for the wrong treatment site.

Prostate patient, we've got eight different locations. We have one location with two patients. So, we have a total of nine patients.

And, in the first one, there were two patients with palladium-103 implants. The medical events were identified by the regulator.

They identified irregularities with one of the authorized user's practices and they looked at the procedures that he had done and identified two medical events where one patient received 37 percent and the other received 66 percent of the prescribed dose.

The next licensee was also identified during inspection. And, in this case, the dose was 73 percent of what was prescribed. There was not any additional information on this particular case.

We have a partial dose was intended, but the full dose was given. It was a human error. They didn't confirm the documentation of the implanted dose and so they thought it was -- it was supposed to be a partial

dose with one accelerator boost and, instead, they gave a full dose.

They delivered a different from what was ordered.

In the first case, it says they were supposed to administer 18,000 rads, instead, they gave 14,000 rads. And, they ordered an air kerma but it was not prescribe in air kerma.

In the second case, they didn't give you why it was different, but they ordered -- there was a difference between what was ordered and what was delivered.

The difference was about 22 percent, so it sounds like it's probably an air kerma versus millicurie event.

Wrong site, so for at least two of the cases, the wrong site was attributed to poor or uncalibrated ultrasound devices.

In the first case, 30 percent of the seeds were planted outside of the treatment site.

In the second case, all of the seeds were implanted into the penile bulb and the dose to the unintended area was 10,000 rads.

Another wrong site, 20 of the seeds, 29 percent of the total prescribed, were implanted into the

bladder.

In this case, the median lobe of the prostate protruded into the bladder and so 20 of the seeds were put into the bladder.

So, their corrective action was procedure modification and additional training of personnel.

Moving on to the HRD Teletherapy Gamma Knife modalities, the 35.600 events, there were a total of 17 for the HRDs, 16. That's not expected, most of them are going to be in HDR.

The first location was not specified. There was one medical event for a nose, there were 11 for gynecological procedures, three for breasts and then we had one Gamma Knife medical event that had eight patients involved.

So, they are broken down into what was the basic cause, wrong patient, one error, bad treatment plan, three medical events, wrong site - seven, source fell out - one, physicists error - two, and equipment problems and failures - two.

So, the one that wasn't specified, the patient received a less dose than prescribed. But the reason it's a medical event is because they treated the patient with someone's treatment plan.

So, they're not retraining people and

requiring them to verify the patient's identity.

In the nose, they wrote the written directive. They gave it to a junior physicist to develop the treatment plan. He didn't develop the treatment plan correctly and so they administered over 71 percent more dose than was in the written directive.

So, the other interesting part of this is the authorized medical physicist and the authorized user, neither one of them identified this before the treatment was given. So, even though it was reviewed by both.

Now, we move into the gynecological ones. I have 11 of these. The largest number is seven and for wrong site, and many of them in the wrong site are going to have radiation induced damage to skin and other body parts.

So, they were trying to administer to the vagina and the outer vaginal mucosa and the upper thigh received the entire dose.

The applicator was improperly placed and the sources were inferior to the treatment site and exterior to the treatment site and they had vagina burning.

The next wrong site, another case where the sources were inferior to the treatment site and exterior

to the opening of the vagina and they ended up with radiation burns.

And, the contributor that they attributed to it was that they had poor film quality because the patient was obese and they thought they had it in the proper location but they were off considerably.

We had two skin radiation burns on both upper thighs. The skin dose was 4,000 rad, a depth of two-tenths of a centimeter. And, there was also 33 percent less dose to the intended site than prescribed.

And, in this case, they attributed it to either the assembly of the vaginal cylinder application was done incorrectly or it became loose while in the patient.

Another wrong site, fraction dose was delivered to the wrong site.

In this case, there were several physicians involved. The first physician gave the first fraction, the second physician gave the second fraction.

Even though it said the first fraction was given correctly, the second physician had difficultly inserting the applicator due to edema and tenderness and went to a smaller applicator.

And then they reviewed the post-treatment images from the week before and found that the source

was at least seven centimeters short of the intended position.

Another wrong site, in this case, the second fraction, they had a close-ended catheter but it wasn't fully seated. They were about 15 centimeters proximal to the prescribed treatment site.

Now, their corrective action is to verify the position of the cylinder and the length of the transfer tube catheter.

Another wrong site, this was the tissue three centimeters inferior to the treatment site received 400 rad.

In the post-treatment imaging, they realized that the cylinder applicator had become loose from the holder and it shifted three centimeters.

They are now going to verify that the applicator is immobilized and that the clamp is where it should be.

Another wrong treatment, in this case, the treatment site received only 20 percent of the intended dose. They inserted the vaginal cylinder three centimeters distal to the vaginal cuff.

They all -- their corrective action is to always use four segments. They didn't indicate whether they used fewer or what happened. But, now they're

going to use four. And, they're going to pay close attention to patient movement. And, they're going to do additional imaging.

Source fell out, the physician enters the room and finds the cylinder on the treatment table. So, there was a failure to secure the cylinder in place and the inability to view the cylinder from the camera. So, they weren't able to identify it earlier.

So, they administered 1,200 rad instead of 1,800 rad.

Physicist error, this is -- I could have also put this in wrong patient. The physicist put up the correct treatment plan and there was a delay and so he pulled up another treatment plan and was looking at it.

So, they inadvertently selected and delivered an incorrect treatment plan on the third fraction.

So, they're now going to verify the treatment plan.

This -- I'm sorry -- the last one wasn't where the physicist brought up the wrong patient, this is the one with the wrong patient.

The last one, they just had multiple treatment plans, they brought up the wrong treatment

plan.

In this one, the physicist had the right treatment plan up, there was a delay. He decided to pull up another one and review it and then the patient is brought in. And so, the physicist repeats the parameters from memory but not by looking at the treatment plan.

So, they gave the wrong treatment to the wrong patient.

Equipment problems, I didn't get a lot of information on this one, but two AMPs felt they had to stop the procedure. So, they engaged the emergency stop. They terminated the treatment. They retracted the source in the shielded position.

But, when they went to restart, they found that the timer wasn't counting down. The timer was increasing.

So, at that point, they decided that they should just terminate the treatment. There was a problem with the device.

They called in the manufacturer. I don't believe the manufacturer was able to replicate their problem.

Now, we've got three breast treatments, all of them are with the SAVI device.

You've got 3,000 rads to an unintended site. They didn't realize they hadn't given the right procedure until the patient came with pain and redness at the incision site.

They had to remove 21 cubic centimeters of tissue. They had to suspend the treatment while they investigated the problem areas. And, they've decided to use a second physicist for an independent evaluation of the treatment plan.

Many times with a SAVI device, it's because they confuse the tip end from the connector end and they believe they're giving the dose within the SAVI, but they're actually giving it outside into the skin.

Another SAVI medical event, and this case, they gave the full 13,000 rads to the entrance site. And, this was definitely one in which they delivered it to the connector end and not to the tip end.

So, the dwell positions within the applicator were not accurately reconstructed in the treatment planning computer. And, they had difficult identifying the starting position and the multiple catheter HDR treatment within the system.

And, the final one with the SAVI, the fractional event occurred while they were sending out the check cable. So, they gave very little of the dose.

And, they determined that the check cable was frayed about a half a centimeter behind the weld junction and it ends up this facility had three other cables, or a total of three cables, with similar fraying.

In talking to the inspector that went out on this inspection and looking at the images, the licensee believed they had to do a quality control test or quality assurance test with a very sharp bend in the guide wire.

And so, they did essentially a 180-degree bend in the wire and that was not what the manufacturer is asking for. And, that put too much stress on the -- they believe they put too much stress on the cable and was the primary reason for the fraying.

And, we haven't seen this issue with any other licensees.

Moving to another modality, this is the Gamma Knife. And, this is one of the earlier Gamma Knives. This is not the Perfexion, this is one with the helmet and with the collimator plugs.

And, in this case, page three of the written directive said where the plugs should be, but it was absent from -- during the equipment preparation.

And so, they didn't put plugs in where they

should have put plugs in. Instead, they had collimators. So, they received -- so they gave 71 rem to the wrong site.

And, from now on, they're going to move the plug use to the first page so that they don't have a problem with having it misplaced and not finding it.

So, now we move into 35.1000 which are our other medical uses or emerging technologies. We had 20 medical events involving 31 patients.

The Perfexion had one medical event involving eight patients and then we had I-125 seed localization, one medical event, Yttrium-90 microspheres, we had 18 events, TheraSpheres had eight with 12 patients, SIR-Spheres had ten with one patient each.

So, for the Perfexion, the manufacturer came in and did some servicing. And, when they did the servicing, they did a workaround or a shortcut or something so that when they aligned the table, it was misaligned.

And, they went back later and determined that this table was misaligned for eight patient treatments.

And so, Elekta, the manufacturer, is still evaluating the service issue. And, these eight

administrations may also be abnormal occurrences.

For the radioactive seed localization, this is a diagnostic procedure, but using a seed that could be a therapeutic seed.

So, in this case, due to illness, the patient wasn't able to return in the five days and didn't have the seeds removed until 26 days after implantation.

And so, the patient received 83 rads instead of the 18 rads.

And, the programmatic review identified that there were other patients that also did not come back within the five days and they used the term "much later than five days," but that those patients did not receive a medical event because of the dose criteria.

For the Yttrium-90 microspheres, this is generally out largest group of medical events, so I'm going to go through the TheraSpheres first and then when I finish the TheraSpheres, I'll go into the SIR-Spheres.

We've got multiple patients, five patients in one case, we've got the wrong site. We've got low flow rate in arteries. We have kinks. We have radiation detector for two cases and remained in the vial of the tubing for two.

So, there were five patients that were administered less than 80 percent of the prescribed

dose. And, they discovered this after the fact when they did imaging of the tubes and they discovered the excess dose was found in the hubs of the catheters. And, all patients were treated with small catheters.

The next medical event was that they administered it to the wrong lobe. They intended it to go into the left lobe, they delivered it to the right lobe.

So, they injected the microspheres into the wrong hepatic artery.

Next medical event, they administered less than they had intended and they attributed it to the size and physical condition of the patient's arteries. It caused low flow and because of the flow, they couldn't get all of the microspheres in.

The next administration was less than they had expected because they had kinking that was noted at the junction of a rigid hub and so the microspheres didn't go into the patient.

The next administration is about 62 percent of what was intended. After they completed the procedure, they found out that their Rados detector erroneously indicated zero mR per hour which would indicate that the microspheres were all into the patient and they found out later that the Rados detector was

erroneous and that most of the microspheres were left in the vial.

The next case was another problem area with a Rados detector that they -- a different licensee said contributed to the event where the activity was concentrated in the plunger attached to the vial.

Next medical event, the microspheres were trapped in the vial for some unknown reason.

The next medical event, most of the dose remained in the D tubing and with lesser amounts in the micro-catheter and in the vial.

So, these are cases where the microspheres just don't make into the patient.

And, let's move to SIR-Spheres, we have the wrong site, four of them in the wrong site. We have an error in calculation. We have two delivery system issues. We have one operator error and crimping or occluded catheters, the tube.

Okay, the first one was, this was a facility's first yttrium-90 microsphere patient and, instead of putting the microspheres into the hepatic artery, they put them into the renal artery. And, they gave a dose of over a thousand Gray to the kidney.

And so, they have decided that they are going to make more formal written check lists to

complete prior to the administration. They're going to have additional mapping images and make sure that the catheter is where it's supposed to be. And then, a second physician will review things.

Next wrong site, the microspheres went -- some microspheres went into the stomach. In this case, they put in the post-treatment scans, they indicated the microspheres were in the stomach. They calculated that about 54 rem was delivered to the stomach area.

Small bowel, in this case, the physician felt that the microspheres were not going in the right place so he stopped the treatment.

And then, they imaged the patient and they discovered that 3,000 rads had gone to the small bowel.

Wrong liver site, so in this case, they administered more radiation than they had expected to the posterior portion of the right lobe.

What they did was they gave an administration intended for the anterior portion of the right lobe of the liver. They had a color coding procedure in place. They didn't have their color coding correctly.

So, they've decided to discontinue the color coding and only have one dosage of microspheres at a time in the interventional radiology suite.

So, in this case, they had two different administrations that were supposed to be given, it's one after the other and they gave the wrong one first.

Dose calculation error, in this case, the physician -- there was shunting and so the physician prescribed an activity based on 20 percent of the lung shunting.

But, there was also a pre-reduction and a post-reduction activity value on the written directive. And, when they calculated the activity that they wanted to give, they used the wrong number. They used the pre-reduction number to calculate what they were going to give and they should have used the post-reduction number. So, they gave too much activity.

We have less administration here. In this case, they had air bubbles that were collecting in the tube. And so, they decided that they needed to stop and see what was going on with the air bubbles.

And, they discovered that the kit was set up incorrectly, that they air was entering the device through an uncovered needle.

We don't get a lot of medical events from setting up the -- recognizing that the device is set up incorrectly.

Then, we have another medical event which

is not quite -- a little more than half was administered and the device came apart during the procedure and the microspheres were lost in the apparatus.

We don't have too many medical events for devices coming apart during a procedure.

So, those two cases are device-related issues or poor training on the facility for putting the devices together correctly.

We had 42 percent delivered during the set up. The patient's catheter was disconnected to flush out air bubbles. We had another one with air bubbles.

But, in this case, they forgot to reconnect the catheter and administered the microspheres without reconnecting the catheter and they didn't go into the patient.

Then they had another one for 78 percent. They had crimping in the tube near the three-way stopcock and the manufacturer determined the cause was abnormally high concentrations of microspheres during administration.

We have 52 percent of the dose delivered. The physician concluded that the catheter was clogged when injecting the microspheres and because he was meeting considerable resistance.

So, they lost some sources when the

catheter was disconnected. And then, the manufacturer looked at it and decided that there was blood in the catheter and the blood in the catheter caused the microspheres to clog and that it wasn't sufficiently flushed prior to infusion.

And those are all the medical events that we saw in FY 2015.

I will tell you that there were probably about 78 medical events that were tagged in NMED as medical events, but in reviewing them, they were really on 57 that met NRC's criteria.

CHAIRMAN ALDERSON: Well, thanks, Dr. Howe for that thorough report.

I have a couple of comments and then we'll ask the ACMUI if they have questions or comments.

Now, I'm always going to assure all my colleagues are always sad to hear of these individual medical events and the patients who incurred them.

When we look at these reports, we would try to look for some trending, though, that would give us some idea of how useful interventions could be recommended or made.

So, I have just two comments the trending.

Given the low number of these events, as Dr. Howe stressed, compared to the overall number of patient

encounters during a year, when we go back to the table that was on slide three, these are very, very small numbers of events. And one would, you know, question the statistical nature of these events from year to year.

The question I have is that, we have here two years and, of course, we've doing -- you, the NRC, has been doing this for a number of years. So, in fact, you have data already in your warehouse of FY '13, '12, '11, other years.

I wonder if it would be useful to the Committee, instead of seeing two years, to actually see, let's say, five? Because you already have the data, it's not a lot of work.

And so, if under 35.400 here, it says five and then nine or ten, that really doesn't worry us, but if it were one, one, one, five, nine, we might say, my goodness, there might be a trend there and we'd want to focus on that.

So, I just make the general suggestion that perhaps since the data are available that we simply report five years instead of two.

Do I have comments from the Committee on that?

Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Well, I think the problem, and this comment has been made before, without knowing the denominator, an impaired trend could be misleading.

I think the use of microspheres, for example, continues to increase. So, you would expect a proportional increase in medical events.

So, I'm not sure that multi-year trending without knowing the denominator would be helpful. And, in fact, it might be misleading.

CHAIRMAN ALDERSON: And so, my response to that comment, I understand that concern. Is that without multi-year trending, you won't see it anyway.

And so, if you do multi-year trending and you see something, then you can ask that question and then you can find the answer is that there are a lot more procedures and so we don't need to worry.

But, if you don't do multi-year trending, you'll never know it even it does happen.

That would be my response to that question.

DR. HOWE: And, I think for the Yttrium-90 microspheres, we always have many more medical events from the Yttrium-90 microspheres because of delivery problems and it's probably an order of magnitude higher in medical events than any other modalities that we're

looking at.

CHAIRMAN ALDERSON: Are there any other -- yes, Mr. Costello?

MEMBER COSTELLO: Yes, I agree. I think having five years would be good. And, I'd hope that new modalities like 35.1000, that what we'd see would be a learning curve, that there might be some in the beginning of it, might be more then as time goes by even with increasing numbers of treatments, I would hope that the percentage of that would go down.

CHAIRMAN ALDERSON: Other comments on that suggestion?

Yes, Dr. Palestro?

MEMBER PALESTRO: Yes, I think your suggestion to look at trending is certainly very useful and I don't want to complicate things with un-founding issues, but I think just looking at the numbers, or I should say, rather than just looking at the numbers, looking at trends that are increasing or decreasing.

I'd also like to look at the individual events themselves. For example, when you're talking about TheraSpheres and so forth, you have things like the wrong site, low flow reads and so forth to see are there particular subgroups in which these events are occurring.

CHAIRMAN ALDERSON: Yes, so, that's the --

DR. HOWE: So, in other words, what you're looking for is something similar to this slide where I've given a reason?

MEMBER PALESTRO: Yes, yes.

CHAIRMAN ALDERSON: Yes. Okay.

DR. HOWE: In addition to the five?

CHAIRMAN ALDERSON: Yes, that's a good comment. That's an excellent comment, I accept that as an amendment to the suggestion.

Are there other comments from the ACMUI?

Yes, Mr. Ouhib?

MR. OUHIB: Yes, Zoubir Ouhib.

I think what I would be looking for is that looking at all these errors, what is the common factor. And looking at that, I see like quite few that really are training-related type of things.

You know, a device that's disconnected and you're still injecting, perhaps even the use of the detector and so on and so forth.

So, I think there's a lot that's sort merge toward that component.

CHAIRMAN ALDERSON: Good.

Yes, Mr. Costello again?

MEMBER COSTELLO: And, these comments, Dr.

Howe, I think are appropriate.

I think that the depth of investigation that the various regulatory agencies do varies a lot from event to event.

And to some, they do get closer to a root cause and some others, they just say, operator error. And, I think that it's hard to evaluate the cause of these things when I think the depth of the investigation varies so much from event to event.

I think if you'd look at the stuff that's in NMED, you'll see that, that some of those are some superficial review and some of them, it's a real in depth one.

CHAIRMAN ALDERSON: Yes? Dr. Langhorst and then Ms. Weil?

MEMBER LANGHORST: Dr. Howe, I always appreciate your report on this because it really condenses things down and it really is, I know, a whole lot of work.

Mr. Costello mentioned one of my questions, so thank you, Frank, for bringing that up on the variation. Because, it's about a little more than half are from Agreement States rather than NRC licensed states. So, there's lots of variability between NRC inspections versus some Agreement States. So, I know

that's a variable.

One suggestion I have for your acronyms for your fiscal year, would you always put down that it's October 1st through September 30th? Because fiscal years are different for all sorts of different people. And, I think it'd just be easily put in there.

But, the one question that I have is, I know there's been previous discussions about making NMED or some portion of NMED data a little more available to licensees as a whole. Because that isn't necessarily available to all licensees.

And, I just wonder if NRC is considering that more?

DR. HOWE: We've looked at that quite extensively and, for a number of reasons, NMED will not be available to the public.

Doug?

MR. BOLLOCK: But, Donna-Beth's report and I believe Dr. Suh's report and the next meeting, those are now available on our public website. So, these slides, if they're not already available, they will be shortly after this meeting.

And, that's the plan to take these, you know, and they have been, if you look at the 200 pages of slides that are up on the presentation. But now, we

specifically pull these presentations out to make them easily available and easier to find for licensees, general public in regards to medical events.

DR. HOWE: And, they'll be on the medical tool kit.

MEMBER LANGHORST: Thank you very much. I think that'll be very helpful for licensees. It may not give them all the data that is at least available, but it certain is helpful.

And, I don't know if there's any way to tie things to event notifications because those are also on the web. But, at least that might be something else that could add to a licensee's knowledge.

So, again, that would be a lot of work and I appreciate that amount of work.

CHAIRMAN ALDERSON: Ms. Weil was next.

MEMBER WEIL: Thank you for this report, as always staying --

DR. HOWE: Can you turn your microphone on, please? You should get a green on it. There we go.

MEMBER WEIL: It would be useful to know, in all cases, what the corrective action was and the outcome for the patient.

I assume when you don't report it, it's because it has -- that information's not available to

you.

DR. HOWE: That's correct. Not everyone give a corrective action. Not everyone gives the effect on the patient.

Many times, they'll write, there's no adverse effect expected for the patient. I only have a short amount of space on the slides, so I may not write that statement every time.

But, I feel like the ones with the radiation burns and the major effects should be--.

MEMBER WEIL: Does it cost the -- I mean, not money, but is there a cost to the licensee for not providing information about the corrective action? Do you go back, do they get dinged again for an incomplete report?

DR. HOWE: We try to get as much information as we can. We have a contractor that runs the NMED program and he tries to get information and they try to go back to the Agreement States. But, sometimes you just can't get any more information.

If it's an NRC licensee, it's fairly easy for us to go back to the Regions and ask for additional information and get it. But, it's a little more difficult on the Agreement States.

MEMBER WEIL: It seems to me that there's

an opportunity for, you know, evasion and obfuscation on the part of the licensee by not providing that information. And, that shouldn't go unpunished, if you will.

MEMBER COSTELLO: Can I make another comment?

CHAIRMAN ALDERSON: Yes, Mr. Costello would like to comment on that.

MEMBER COSTELLO: These reports really are provided by the regulator; the information, I think comes to the NRC from the States who get the information from the licensee.

So, it's not necessarily true that the licensees is withholding things. It comes out of the interaction between the regulator and the licensee, how much information I get.

So, maybe if the regulators pushed a little harder, we'd get more information. It's the licensee's fault necessarily that all the information's not there. Sometimes it is, but sometimes we, the regulator, could be more aggressive in getting that information.

MEMBER WEIL: One other comment, if I may?

It's important to note that many of these events are identified by the regulator during an inspection as opposed to being self-reported by the

licensee.

So, when we're looking at trending and the denominator, we can't really -- we shouldn't assume that this is the number of medical events that actually occur. This is just ones that surface.

CHAIRMAN ALDERSON: Dr. Zanzonico had a comment to make.

DR. HOWE: Let me just a quick comment.

I report the information that was reported in the fiscal year because, if there was a medical event that happened three or four years that wasn't identified three or four years ago, if I just reported what happened in that year, that would be lost forever.

But, I report what's reported in that so that we may have events in here that are a couple of years-old or a year-old or six months old.

And, I do that to try to make sure we have captured everything that is available to us.

CHAIRMAN ALDERSON: Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: I have a comment and a question.

The comment is, if you haven't seen these procedures firsthand, they are very complicated, very labor intensive and there's lots of opportunity for errors.

And it's remarkable that if these -- this is microspheres I'm referring -- that if these numbers are anywhere near accurate, it certainly is under reporting because it's self-reporting, it's remarkably low for procedures of this complexity.

And, I know, at least at Memorial, the interventional radiologists are getting, what's the word, more adventurous and are doing more and more difficult cases by this procedure because they've had such results.

And, that, inevitably, I think, even in very skilled hands is going to lend itself to events that may or may not be construed as medical events.

But, that's just a comment.

But, my question is, it struck me that there were several microsphere events, the ones on slides 42, 47 and 48, which, perhaps, were patient intervention.

And, I guess the question is, you know, unexpected or abnormal anatomy or complex anatomy that led to microspheres being deposited in the wrong location.

In other words, it wasn't clear that there was an identifiable user error in some of these.

DR. HOWE: I only remember one where it said that the vessels were giving a really hard push and

so he stopped.

VICE CHAIRMAN ZANZONICO: Right.

DR. HOWE: The size or the physical condition of the patient's arteries caused the low flow condition. I don't remember another one being attributed --

VICE CHAIRMAN ZANZONICO: Well, I don't think truly, if any of them truly were over and not medical events.

But, I guess my question is, do you ever sense that with the new guidance that's being prepared, if that -- if any of these would or would no longer be considered medical events?

DR. HOWE: With the existing guidance, we had a provision in the existing guidance that, if you had arterial constriction or other things and low blood pressure and there were certain things you had, if you had those and you could document that on the final written directive, then it wouldn't be a medical event.

So, that's in the existing guidance. And, Dr. Tapp will talk to us more about the guidance that's being developed.

So, we do have one provision already and then the ACMUI has given a couple of other things to look at and that's coming out in this --

CHAIRMAN ALDERSON: All right, so is there another comment? Did you have your hand up, Steve?

Mike Fuller has his hand up, also. So, Steve, you'll be first, Steve Mattmuller and then Mike Fuller.

MEMBER MATTMULLER: Steve Mattmuller.

Just to go back to the first two events regarding the bulk dose of technetium and it really struck me as being odd because that would entail that someone would have to take a bulk dose of vial of technetium and draw a dose from it and not assay it --

DR. HOWE: Absolutely.

MEMBER MATTMULLER: -- and then inject it.

And, so it struck me as being very odd.

And, actually, in the one report, it says it's a bulk syringe. And then, in the other one, it doesn't say vial, so I'm assuming that -- and it's always hard because it's always incomplete data or information in these report.

So, my assumption for that one is that they're both bulk doses and syringes which makes it a little bit, I don't know if it makes it worse for this situation, but a little bit easier to get mixed up.

And, that sticks out to me because I thought, gosh, that could happen at my place because we

do prepare a large kit of Myoview.

And then, my initial thoughts was to put it in a vial and ship the vial to our sister hospital two miles away until I realized my packaging was approved only for a unit with syringe carrier and not in the multi-dose vial.

So, for some of you who are wondering what I'm going to do when I get off of this table, and I hope my administrator is not listening to me because this is a task I've put off for a few years. I need to do testing of my packaging for multi-dose vial because that's the preferred way of shipping it.

So, for those two, I think it's more of a syringe where it would be easier to mix up and, unfortunately, for those two, that's what happened.

A little worry you need for other reasons, but it's a very uncommon practice. So, surprised this has happened.

In regards to the event that happened at Sloan Kettering in New York, I wasn't sure if this was really a medical event.

DR. HOWE: Because I did not identify locations, you will have to give more of a description.

MEMBER MATTMULLER: Okay, sorry about that. So, it's --

DR. HOWE: What modality are we talking about?

MEMBER MATTMULLER: We're talking about the I-124.

DR. HOWE: Oh, okay, so that's the pediatric case.

MEMBER MATTMULLER: Right. And, I-124 is a beta emitter and so, it's not a therapeutic radionuclide, it would be used for diagnostic imaging, so I'm not sure why it would need a written directive.

DR. HOWE: So, the --

VICE CHAIRMAN ZANZONICO: Could I -- I was involved in that.

MEMBER MATTMULLER: Yes, yes.

VICE CHAIRMAN ZANZONICO: None of it was my fault.

MEMBER MATTMULLER: So he says.

DR. HOWE: Of course.

VICE CHAIRMAN ZANZONICO: This was an investigational study for treatment of cerebellar pontine glioma which is a uniformly fatal childhood brain cancer.

And, in this study, the surgeon, under image guidance, inserts a catheter through the skull directly into the tumor in the cerebellum. And,

because the I-124 was being delivered so locally and it is a beta emitter, it's a therapeutic dose.

So, this is --

MEMBER MATTMULLER: It's a positron emitter.

VICE CHAIRMAN ZANZONICO: Yes, it's -- well, which is a beta.

MEMBER MATTMULLER: Yes.

VICE CHAIRMAN ZANZONICO: And so, you get the local dose. You get on the order of 1,500 rads per millicurie instilled to the tumor volume.

So, this is being used as a true theragnostic study.

MEMBER MATTMULLER: Theragnostic?

VICE CHAIRMAN ZANZONICO: You both image the therapy dose by PET to do the dosimetry but you also with the same administration delivering presumably a therapeutic dose as well.

MEMBER MATTMULLER: Okay.

VICE CHAIRMAN ZANZONICO: So, in a way, it's a new category. It's a true theranostic study.

CHAIRMAN ALDERSON: Thank you.

Mr. Fuller?

MR. FULLER: Yes, Mike Fuller.

Dr. Alderson, I know you had asked if maybe

we could expand the period of time under which we are reporting to the perhaps five years. And, at the risk of having Donna-Beth get mad at me, I was going to suggest to perhaps think about, because it would take a lot of work for us for one year and then each year after that, I don't think it would be that much of a burden on us.

But, we have, as you've indicated, several years of data and, at least and to create maybe some curves over a longer period of time, so you can might see -- because then you could sort of tease from that long-term trends or longer year curves that you could observe and then still the shorter term, three to five to seven, what have you, that information would also be available.

So, I would just like to offer that, if you wanted more than five years, you know, don't hesitate to ask for that again.

The first year, it would take quite a bit of work and we'll find somebody to help Donna-Beth. But then, after that, it's really not going to be much of a burden on us to just kind of keep up with the long-term data and present that.

CHAIRMAN ALDERSON: Well, thank you.

So, we heard earlier that there may be many

confounding factors if you look out over time and we made the suggestion that, if we found any trends or thought there were any trends, then we could ask about those confounding factors in those issues.

And so, if the Committee is willing to accept Mr. Fuller's volunteer motion, we could, in fact, look forward to learning over a period of time about a little longer spectrum of time regarding the medical events.

Would someone wish to make a motion to that effect?

VICE CHAIRMAN ZANZONICO: Sure.

MEMBER COSTELLO: Moved.

CHAIRMAN ALDERSON: So moved, says Pat and Mr. Costello.

Is there a second to that?

MEMBER COSTELLO: Second.

CHAIRMAN ALDERSON: Is there further discussion?

Hearing none, those in favor?

(Chorus of aye.)

CHAIRMAN ALDERSON: Opposed or abstaining?

That is accepted unanimously.

Thank you, Mr. Fuller.

Yes, I believe Mr. Costello has a comment before we adjourn.

MEMBER COSTELLO: Yes, it strikes me that the stuff this Committee has been working on over the last year, we've talked about the guidance for shunting and people keep thinking about where the guidance for shunting, it might affect some of these events that you talked about as being taken from events that is perhaps, not even events.

We talked about -- have talked about forever going from dose-based regime to an activity-based regime for permanent brachytherapy. And, I think we had a case that are like 66 percent of the dose, for I assume on a dose-based. And, I don't know if that would have been an event on activity-based.

I don't want to hear, I'm just saying it could be affected by it.

And also, we mentioned patient intervention. Well, we've made recommendations for patient intervention. I think we're being held up for more pressing work.

But, I think that when that's adopted, they also affect, maybe even reduce, the number of medical events if you take a broader view of what patient intervention may be.

These are all three topics that we've been working on over the last year.

CHAIRMAN ALDERSON: Yes, excellent.

I will ask at this point if there are any members of the public who wish to comment on any of these recent discussions over the last several minutes, please speak now.

Hearing none, I assume that there are no comments there.

So, I think that we're now ready to break for a short time. We will reconvene at 3:00 which is about 17 minutes from now to continue the agenda.

(Whereupon, the above-entitled matter went off the record at 2:43 p.m. and resumed at 3:01 p.m.)

CHAIRMAN ALDERSON: We're going to call the meeting to order and get started on the next section.

So, we're ready to hear the report on Medical Event Reporting for All Modalities Except Permanent Implant Brachytherapy and John Suh will be reporting for the Subcommittee.

MEMBER SUH: On October 9, 2015, Dr. Ennis provided the ACMUI with the annual presentation on the previous fiscal year's medical event reporting which still remains extremely low.

Dr. Bruce Thomadsen, the outgoing ACMUI

Chair discussed the incident at his institution where there was confusion as to whether or not it constituted a medical event.

As a result, this led to the formation of this Subcommittee to look at that report, medical event reporting for this.

So, in terms of history of medical event reporting, since the 1970s, there's not been much change in how medical event reporting has been performed.

In 1991, medical event criteria included the difference between the prescribed and administered dose of greater than 10 percent. So, that's kind of been the backbone in terms of the history of medical event reporting.

As a result, the current definitions may not be appropriate given the advances and technologies currently used, particularly in radiation oncology. 10 CFR Part 35, Subpart M covers these reports.

In terms of the Subcommittee discussions, the Subcommittee discussed the current medical event reporting criteria under 10 CFR Part 35.3045.

The Subcommittee also reviewed different scenarios in which the current medical event criteria were ambiguous and, therefore, required possible modifications.

And given the spatial precision of modern therapies, a slight shift in significant dose in nearby tissues or parts of organs can occur.

And, just to review the current report notification of medical events from 35.3045, a licensee shall report any event except for an event that results from patient intervention in which the administration of the byproduct irradiation from byproduct material results in the following.

So, a dose that differs from the prescribed dose or dose that would have resulted from the prescribed dosage by more than 5 rem, effective dose equivalent, 50 rem to the organ or tissue or 50 rem shallow dose equivalent to skin.

And, total dose differs by prescribed dose by 20 percent or more. The total dose differs -- delivered difference from the prescribed dose by 20 percent or more or falls outside the prescribe dosage range or the fractionated dose delivery differs from the prescribed dose for a single fraction by 50 percent or more.

Another possibility is where there is administration of a wrong radioactive drug containing the byproduct material, administration of a radioactive drug containing byproduct material by the wrong route

of administration, an administration of a dose or dosage to the wrong individual or human research subject, an administration of a dose or dosage delivered by the wrong mode of treatment or a leaking sealed source.

And, in terms of other scenarios, the licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of a byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiologic system as it's run by a physician. I should note that's bolded in red and I'll highlight that in a little bit.

The licensee shall notify by telephone the NRC Operations Center no later than the next calendar day of the discovery of the medical event.

That's just some background in terms of the current definition and the notification of a medical event.

So, in terms of medical events that would need to be covered for the variety of treatment options, you can see that are listed here.

Treatment options such as selective internal radiation therapy, and we heard a little bit about the SIR-Sphere and TheraSphere, high dose

brachytherapy which is used for many different organs right now, including breasts, Gyn, lung, prostate and skin cancer, also for Gamma Knife radiosurgery or ViewRay, or low dose rate implants that are non-prostate related, low dose rate meshes which are sometimes used for some thoracic malignancies, unstilled sources which could be intravenous or oral and IPAC brachytherapy.

We had discussed whether or not defining medical events by modalities was perhaps preferable and the thinking was that it may be easier for the licensee to determine if a medical event occurred.

It may be easier to inspect and regulate and it may facilitate programs, procedures and education to prevent future events.

Since the delivery systems at risk are very different for each of these modalities, the specific medical event for each modality may provide some advantages, but the Subcommittee did not favor modality-specific medical events just because that would require individualizing the definition of medical events for each of the modalities which was just shown previously.

In terms of recommendations from the Subcommittee, the Subcommittee felt that medical event reporting should allow identification of the medical

event and provide a forum to discuss how to avoid and reduce the likelihood of such an event.

The definitions of a medical event reporting need to be broad, simply and consistent so reports are easily applicable by an authorized user, applicable by regulators and process focused to eliminate any ambiguity of what constitutes a medical event.

The Subcommittee believes that the part of the definition based on, quote, unintended permanent functional damage to an organ or a physiologic system as defined by a physician, end of quotes, needs reconsideration, especially the word unintended.

The Subcommittee also believes that the creation of a subsection within the current definition of medical event reporting be considered to address the newer oncology modalities that prescribe doses to volumes.

And, finally, the Subcommittee believes that any proposed changes must not encroach on the practice of medicine.

Thank you.

CHAIRMAN ALDERSON: Thank you, Dr. Suh.

This report is now open for comment.

Mr. Costello?

MEMBER COSTELLO: Well, you gave a lot of good arguments. You have a lot of events to the regulator and then you said the Committee decided not to go that direction.

As soon as you got to that point, I was thinking why not go that direction?

MEMBER SUH: So, it's -- there's a lot of different -- so, again, there are, I think, benefits to try and do it per modality. I think the difficulty is going to be to try to define medical events for every single modality is going to be a very big undertaking and it's probably going to a very long time as well.

And, I think it's going to keep it simple and also not create a lot of different what if scenarios.

The thinking was from the Subcommittee is that it's going to be easier if we amended the current definition of medical events rather than try and create separate medical event definitions for every single modality.

And, as you saw in that list, there's about ten different modalities that we'd have to define. And, that, again, would be a very big undertaking to try to do it for every single modality.

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: Sorry, I may be a little

dense these days, but did we have a written report, a draft report? So, we didn't have anything to read on this other than the slides?

MS. HOLIDAY: Dr. Langhorst, this is Sophie.

I think the idea is that Dr. Suh's Subcommittee would be presenting their discussion and this would serve as more like a forum or a discussion amongst the Committee members.

MEMBER LANGHORST: Okay, thank you.

Sorry, I was confused about what it was supposed to be.

MEMBER SUH: Yes, it was a work discussion. So, actually, I had that discussion with Sophie before this talk. So, you were not mistaken.

CHAIRMAN ALDERSON: Further comments from the ACMUI?

MEMBER COSTELLO: I have one other.

CHAIRMAN ALDERSON: Yes, Frank?

MEMBER COSTELLO: Where is the Subcommittee going to go from here? I mean, clearly, the Subcommittee recognizes that -- I'm sorry.

Where is the Subcommittee want to go from here? I mean, clearly, the status quo isn't perfect as you have in your slides. What's next?

MEMBER SUH: So, I think in terms of what's next is I think we will need to start the process of defining what constitutes a medical event for non-permanent implant for any type of radiation modality. So, we're going to need to start that process defining what constitutes a medical event for these.

And, just given the variety of different modalities that are being used right now to treat various conditions, it's going to be a big undertaking. But, I think we need to start defining what that is going to be.

MEMBER COSTELLO: So, this is a work in progress, then?

MEMBER SUH: This is a work in progress.

MEMBER COSTELLO: And, what we can expect over the next, you tell me, period of time is that you'll be briefing us on various modalities that you would recommend that the Committee take and then the NRC take?

MEMBER SUH: Yes.

MEMBER COSTELLO: Okay.

MEMBER SUH: I think just to build on what Dr. Donna-Beth Howe just presented, I think this also gives us an opportunity in terms of, kind of, you know, we're moving more toward, you know, looking at the education composite piece. So, I think this also will

tie in very well as in terms of just what constitutes these medical events.

And, I think one of the things I just want to comment on just from the last part of the meeting, I think having the information being made more public I think is very useful I think for, you know, someone who's been trained to actually look at what they didn't identify as the right patient I think it very important.

I think it's something that, if you look at some of these various modalities that are being used, I think there's definitely best practices that can be learned.

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: I think that's going to be great. I loved it and I can't wait to hear what the Subcommittee comes up with.

I encourage you to look specifically at the 35.1000 guidance documents because sometimes they have some specific guidance about medical event reporting.

I know we'll probably be doing that on the training and experience piece of just what you were suggesting.

So, I just encourage you to look at those to see if there's anything a little different from the 35.3045 definition.

Thank you.

CHAIRMAN ALDERSON: Yes, Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: I just have a more or less a procedural question. I mean, I think we've all learned that when regulations or for, in this instance, medical events are defined in the prescriptive manner and then trying to update them wasn't even possible.

So, I wondering if maybe a middle ground with non-modality specific definitions for MEs are in the red. But, as Sue just pointed out, supplement those with modality specific guidance documents. Because that seems like it would give you the flexibility as new modalities are introduced, so forth and so on, that you can provide concrete guidance to users for those.

But, I mean, I agree putting modality specific definitions of MEs is like after the work will work well.

So, that's just a comment.

CHAIRMAN ALDERSON: Yes?

MEMBER WEIL: You mentioned that you were uncomfortable with the word unintended permanent functional damage in the slide number ten. And, I'm wondering what your thinking is there?

MEMBER SUH: So, we talked about as a

Subcommittee, we really didn't come up with a better word than unintended, but we just felt that the connotation of unintended was probably not what is best suited in terms of what constitutes a medical event.

CHAIRMAN ALDERSON: Yes, Dr. Dilsizian?

MEMBER DILSIZIAN: For example, it's you know, the attention on unintended, for example, you know, I proposed ''unexpected.'' It's not something anybody was intending, it's some -- those kind of things, more of a bad definition than it seems to connote with unintended.

MEMBER WEIL: I can imagine, you know, that in treating a tumor of some sort that you might damage, you might cause functional damage intentionally, though. I mean, it would be part of the therapeutic goal, no?

MEMBER DILSIZIAN: Well, absolutely. But, this is --

MEMBER WEIL: Different?

MEMBER DILSIZIAN: -- unintended events. In essence, if some, you know, we talked about microsphere therapies, it's going in the wrong [location] unintentionally, but it's unexpectedly. So, those are the couple of things I think we're talking about, right?

MEMBER SUH: Yes, yes. You wanted something else for the word unintended, and it's something you felt that unintended was perhaps not the best verbiage.

CHAIRMAN ALDERSON: So, Dr. Suh, is it true then, to follow up on Ms. Weil's question, that when you came back in slide 14 and, as a recommendation, you again brought up this phrase and said that it needs reconsideration, is it primarily the word unintended that is the thing that is the problem in that phrase?

MEMBER SUH: I think that was the concern. I wouldn't say it was necessarily a problem, but I think some people in the Subcommittee felt that that word was not the best word for that.

CHAIRMAN ALDERSON: Right, okay. So, that's what brought it here? Thank you for that clarification.

Other comments or questions from the ACMUI on this report?

Anyone else in the audience that wishes to comment on this report? Anyone here in the room?

MS. HOLIDAY: Dr. Alderson, this is Sophie.

CHAIRMAN ALDERSON: Yes, Sophie?

MS. HOLIDAY: If I may, I guess I just want

to remind the Committee of why this Subcommittee was formed.

If you guys will recall during the October meeting, Dr. Thomadsen, during his farewell presentation had brought up multiple things. And, one of the things that he brought up was that there was an event that occurred at his institution and they thought that it was a medical event.

So, they reported it and their regulatory authority came back and said, no, it's not a medical event.

So, his institution re-evaluated it and they still thought that it was a medical event. So, he formed the Subcommittee because he wanted the Committee to maybe look at clarifying the medical event reporting criteria and maybe this discussion, I think, the objective is to get the Committee as a whole to maybe discuss different instances at their institutions where maybe similar things had occurred.

And, that way, it could help facilitate the Subcommittee's work.

CHAIRMAN ALDERSON: Well, thank you, Ms. Holiday.

So, would anyone on the Committee like to help us resolve the ambiguity in medical events by

giving us some examples from their own experience? Redacted for the appropriate details, of course.

Yes, Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Yes, well, actually, it was the I-124 incident that was reported as an ME and there was a lot of disagreement at Memorial over whether this was reportable or not.

I did not think it was reportable. And, what had happened was, the catheter was put in place and the infusion, since it's directly into the brain, has to be done very slowly, microliters per minute to avoid brain swelling.

And so, the amount of activity that was injected into the body that was injected in the slow rate of injection meant that the patient was awake with the catheter in place and these are children.

And, in the past, when a small body of activities were used, it was done completely in the OR while they were under anesthesia.

And, the children, people doing what they do, move and the catheter didn't come out, but the connector was loosened.

I think that can be interpreted as patient intervention. Nothing was done incorrectly by the surgeon or anyone else involved with the procedure and

so, in that respect, it was a -- I thought it was not a medical event even though the activity delivered was easily 50 percent from that that was prescribed.

I mean, I think that's the kind of thing where there's sort of a grey area as to whether patient intervention resulted in the under dosing or over dosing or something incorrectly was done that resulted in that and so forth.

CHAIRMAN ALDERSON: So, given, just to follow up on your comment, given, then, that you clearly an expert, didn't feel it was a medical event. How did this event get reported? How was that decided that it should be reported?

VICE CHAIRMAN ZANZONICO: Well, I was -- it was put in by the RSO.

CHAIRMAN ALDERSON: I see. So, it's the RSO?

VICE CHAIRMAN ZANZONICO: It's the RSO's fault. It was.

And, I think it was just a matter of an overabundance of caution and they didn't want the institution to appear to be in a position that something that possibly could be construed as a medical event was being swept under the rug is what I guess.

CHAIRMAN ALDERSON: I got it.

Ms. Weil will be next.

MEMBER WEIL: If you go back to the purpose of reporting medical events, and to see it in a positive opportunities for making a public situation -- these are opportunities for public discussion or public perusal of events that have happened.

Instead of punishing the clinicians involved but rather this is a useful thing if you're going to administer something over a long infusion to a child who is awake, it's useful for other clinicians to know that something got loose and maybe to prevent that from occurring in the future.

CHAIRMAN ALDERSON: Okay.

Yes, Mr. Zanzonico would like to respond to that.

VICE CHAIRMAN ZANZONICO: Yes, right.

CHAIRMAN ALDERSON: And then, we have a couple of others.

VICE CHAIRMAN ZANZONICO: Right. There is an unintended consequence of that and that is that practitioners may avoid this sort of procedure because, you know, these sort of, quote, unquote, risky or non-standard procedures, because it more likely puts them in a position of having to report something that went wrong.

The other point is, these events, even if they're not reported to a regulator of a medical event, are reported. They're reported in the peer review literature as case reports and so forth.

So, the information is the disseminated to the practitioner community. The issue is whether it rises to the level of requiring reporting to a regulator. Even if that is being not met, doesn't mean the information doesn't get disseminated to the people who can use it.

CHAIRMAN ALDERSON: We have many -- many hands are up. Ouhib?

MR. OUHIB: Yes, I'll go back to your question, and that is we really are not -- even if they're not certain or not sure that it's a -- the fact that it's a medical event, you should report it. And then, eventually, the decision will come afterwards.

The other item that I was going to say is, and regarding your case and Bruce Thomadsen's case, I think this Subcommittee can really use these cases and they will help us actually do some more work.

Because then we're looking, well, where is the real issue here? Let's look at this and let's evaluate this. And then, maybe that will help us sort of go in a certain direction.

CHAIRMAN ALDERSON: Thank you.

I think Dr. Ennis was next.

MEMBER ENNIS: Thank you.

Two comments. One, just we've talked about this in this Committee before, but just to Ms. Weil's comment. The reality is the way a medical event is used in institutions is not that idealized version that you just expressed.

Now, if we want to somehow take on and change that whole system and come up with some new idea or some new thing, that's fine. But, that's just not how it is and it has big ramifications for the practitioners in a very public kind of way that can be very uncomfortable or even politically damaging. That's number one.

Number two, just to give a little more flavor to what we are talking about from a radiation oncology perspective, these criteria really fit an era where radiation was given as a big square box aimed straight at a part of the body or maybe from two angles or three angles where the dose that was distributed within the tissue was uniform and large.

And now, what we do is much smaller, précised and less homogeneous. So, there are scenarios that can come up, I'll give you a couple of examples,

that just don't fit.

So, a simple example would be, if I was treating, let's say, the left side of someone's abdominal pelvic area and there are a number of organs in there that are getting exposed just because they're nearby and there's a tumor there.

And, if I sit the patient up in such a way that a couple of inches off, is that a medical event?

The same organs are getting exposed, but differing amounts of them. So now, maybe more of their liver's getting exposed than before. How much more is a medical event? Or is it a medical event?

Their colon is getting -- you get the idea. And, it's not wrong body sites, it's the same body site, it's a little off, volume wise. How much off to what degree?

Another example might be, if I'm treating a volume and it's inhomogeneous now, so, I'm purposefully treating a spot within that -- with double dose and I'm treating some other spots, but half of that dose.

And, something happens where that distribution of dose is not delivered correctly, upside down, wrong -- again, so different organs are getting different doses than what was intended, if you will,

but, again, how egregious was that and what -- how do we define when that reaches some kind of threshold of a medical event?

So, I think from a radiation oncology perspective, this whole volume issue in particular and inhomogeneity just makes it -- the prior things inapplicable.

CHAIRMAN ALDERSON: There was another comment over here. Mr. Costello?

MEMBER COSTELLO: Tomorrow, Mr. Bollock is going to talk a little bit about the OIG report. And, one of the recommendations was to clearly define the purpose of medical event reporting in a publically available document and classify the reporting requirements.

I think the uncertainty is the need for clarification underlies a lot of our discussion. It underlies patient intervention. It underlies the way you talk about with the --

And, with all due respect of what you're going to say tomorrow, Doug, I think it's something that the Committee should consider taking up.

I mean this purpose of the medical event goes back decades, maybe the early '80s, something like that, 1980. It's you know, 36 years old. And, therapy

has changed a lot since 1980. Okay?

And, maybe for clarifying the purpose of it, it's something that the Committee should undertake and make it modern, make it for the 21st century.

And, I'm going to mention this tomorrow after you give your talk, but I think underlying a lot of our discussions that we've had for a while is this lack of clarity, what the purpose of the rule is.

And, reasonable people can differ what the purpose of the rule because it was put out in 1980, it could be clearer now in 2016.

So, that's really a comment. It's, you know, a lot of discussions we've had from prostate and the seeds dose versus activity to, you know, microspheres to patient intervention to a lot of these things. I think what made my mind, would drive some of that is lack of clarity. Why are we even doing this?

And, now, may be the time for the Committee to put its mark on that.

That's all.

CHAIRMAN ALDERSON: Thank you, Mr. Costello, for that comment.

Dr. Langhorst?

MEMBER LANGHORST: Another aspect to what Frank was bringing up is, what is the regulatory

measure? What do you measure?

And, a lot of these differences in dose an inspector cannot do those calculations. And so, is that -- how do you balance that? If it's a dosage of radioactive or a radiopharmaceutical, you can see I was supposed to have prescribed five millicuries. We gave three, that's a -- you can see that. That's right there in the documentation.

But, as far as the dose goes, you have to rely on the institution to make those calculations and so one. And so, it's a difficulty that, how do you inspect on that?

And, I want to address what Laura has brought up, too, is you want your institution to bring those issues forward. And in the, I'll say the idealized way, that's part of your safety culture.

But, you want to be able to bring that forward without fear of repercussion.

And, I'll tell you as an RSO, having to have reactive inspections, I feel the repercussion because it's never, oh, let's see what we can learn, it's what did you do wrong and how can we give you a violation?

I mean, I hate to say it that way, but that's the way it happens.

So, I think we'll be discussing it more as

we talk about the OIG report tomorrow. But, how do you have a regulatory environment with regulations that you have to enforce and also be supportive of a safety culture in bringing those things forward. And, it's not an easy balance.

CHAIRMAN ALDERSON: I think that's an excellent comment.

Dr. Metter?

MEMBER METTER: Well, I think, and you're right, I can give you an example.

Before when Y-90s first came out and the dose delivery was 60 percent. And so, I was concerned and I said this is a medical event. I went ahead before the -- regarding to dose delivered due to stasis, it came out.

And so, I brought it to our RSO and then we found that it [the revised guidance] had just been written the month before in June. And so, it turns out it wasn't [a medical event]. And so, the RSO wrote to my department chair and said, well, no, this isn't met. This isn't a medical event.

I got reprimanded for bringing it up by my department chair. And, I was not supposed to anything like that unless I get it cleared by the department chair who didn't understand what a medical event was.

So, you are correct, there's a lot of other things that go on because they don't anything to look bad for the department, but in the end, it wasn't a medical event, but the process was difficult and, you know, and it's difficult to bring things up like this because of other issues that are involved.

CHAIRMAN ALDERSON: And, these are very important comments and I just want to set a context before I go back to Mr. Costello for the next question is that we all are very familiar with the quality assurance movement. It is everywhere. And, it is said again and again that that is a non-punitive approach. We are all trying to improve.

But, we didn't think that way about the QA movement when it started, go back, I don't know what it was, 15 years ago or so, it was very much punitive in all of our cultures.

But, enough people spoke up and it's not that punitive anymore. It's less punitive.

And so, at some point, as part of these discussions on medical events, we, as a Committee, should consider whether, you know, you've got to start somewhere. We should be speaking up and making it clear that we think that the regulatory culture on this should not be punitive.

So, I just put that out there as an observation. And now, I believe the next comment was Mr. Costello.

MEMBER COSTELLO: So, you brought up, you know, how do we, as inspectors, evaluate these things? And, the real answer is largely we don't. Okay? There's no way I can look at results of a CT and know where the seeds are and calculate dose. I mean, I don't do that.

For many cases, I simply rely and trust our licensees to calculate doses properly and calculate -- and figure out which activities put there properly. And, then that's what I identify.

As far as the punitive, you know, that varies probably from regulator to regulator and I'd say that I think we try not to, sometimes it may feel that way. But, I don't think it's ever our intention to do that.

And, the other observation I had is, often times, we find that it is the better programs that are reporting the medical events. The better -- it's not the, you know, marginal programs who's reporting or anything, they don't report anything because, if I may say bluntly, they wouldn't know a medical event if it fell on their head. Okay?

But, it's the prestigious organizations that have good quality programs that have internal debates whether this is -- they're the ones reporting it.

There are programs, I know, are not the best that we never hear from. I don't have an answer for that. Your institutions rule bound and those are the ones that we get reports from.

So, if we, as regulators, are making you feel -- being punished for doing the right thing, following the safety culture, then we've got to a better job.

CHAIRMAN ALDERSON: Dr. Metter?

MEMBER METTER: I think what you brought up with quality assurance in the past is correct, it was a retrospective thing about, if you didn't follow the rules, you're going to get punished.

Now, I believe the new culture is quality improvement. And so, it's more of a just culture where you're not individually penalized as individuals but more the systems and I think the systems cause this sort of problem. And, I think that's kind of what you're reflecting.

CHAIRMAN ALDERSON: Thank you.

Mr. Ouhib?

MR. OUHIB: Yes, I think you brought a very good point. And, there are some sort of a disconnect. There is a perception and there are facts.

And, I think there was one -- somebody had one slide earlier where it is time to have the ACMUI, NRC and professional organizations sort of get together and discuss this together, basically, to come up with a better, you know, a culture of safety, you know, and everybody is online.

CHAIRMAN ALDERSON: Very good.

Other comments?

Well, I think if there was a concern, Dr. Suh, that this might stop at this point or you had no other --

MEMBER SUH: No, no.

CHAIRMAN ALDERSON: We have resolved that very clearly. So, this is a challenging, interesting area. We're going to hear more about it tomorrow.

Any final comments, Dr. Suh?

MEMBER SUH: So, I just wanted to just to -- I think it's been a great discussion. I think it is very important that, as a Committee, we look at the process and not punish the people. I think it is something that we have to do a better job of.

And, I fully agree that there are some

institutions where a mistake has happened, there's repercussions. And, as a physician and as an authorized user, you don't want to go there.

But, I mean, it's okay John. Not necessarily like that, you know, depending where you are at what institution. So, I think we're getting better at that, but --

You know, and I think the other thing, too, is I think, well, for a lot of physicians, making -- admitting to a mistake is very hard for them to do.

I think sometimes for that -- so, I would venture that there is under reporting that goes on.

And, I think for high quality institutions, you want to do what's right. You want to have a just culture and say, this was not done correctly and, as a result, we need to report it.

And, I do like the fact that there's going to be greater transparency. And, I think one of the things that I can personally do is that, you know, for the trainees that we have, I think it's good for them to read about these events.

Hey, they didn't check the right site. And, one of the things that I think is very important is doing a fundamental time out can avert some of the medical events that we heard earlier today.

I mean, just simply just asking for your name and your birth date and which part of the body are you treating? And, if the patients says you're supposed to be treating here with radiosurgery and I'm going to treat here, I'd better think long and hard before I sit the patient in the machine and push the button.

CHAIRMAN ALDERSON: Those are great comments, Dr. Suh. And so, I think as your Committee moves forward, we'll be able to bring some of those things forward in a more official way.

So, I want to thank everybody who contributed to this very good discussion and to the great Committee report for their work and we'll move forward with this.

Thank you.

So, I think we're ready, if Katie Tapp is ready to start, we're ready to move on to the next presentation which is on NUREG-1556, Volume 9 Update.

DR. TAPP: Thank you, I'm here right now to discuss NUREG-1556, Volume 9 Update.

NUREG-1556 is the consolidated guidance about material licenses. Volume 9 is specific to medical use licenses.

Currently, there are two updates going on

with Volume 9. The first update is associated with the rulemaking. This update is on the bottom here in this chart and its current has just received comments from ACMUI and Agreement States.

As we discussed before, the NRC is looking at these comments and going through the resolutions and initiating to send up the final rule to the Commission.

In addition, there is an update to the sections that are not associated with the rulemaking. That is the top part of this chart.

We have received comments from the steering committee that's involved with updates to all the 1556 volumes and from NRC staff and from the ACMUI members.

We're resolving those comments now and are planning to send this report for public comments.

This revision will not include the updates that are associated with the rulemaking. This will be sent out without those updates.

As you can see from this table, it will be after we get direction from our Commission for that and as well as receiving the public comments for the updates that are not associated with the rulemaking, we'll bring those two together and then we'll issue it for final publication.

The updates not associated with the

rulemaking are associated with comments that were received but not addressed during Revision 2 to this document.

Revision 2 was associated with the NARM rule where we included naturally occurring and accelerated produced isotopes.

In addition, we have new comments from the public and from NRC and Agreement States staff including both inspectors and licensing staff.

We received ACMUI recommendations and we're incorporating those into the documents as well as updates to references that have occurred and get other guidance documents since the last revision.

We're going to reflect the movement of going more electronic-based. This new document will include hyperlinks so we can move throughout the document. It's a very large document, so this will allow movement easily throughout the document as well as to regulations and other guidance documents.

We are also adding consistencies between all the volumes. There is 21 volumes in NUREG-1556 and we want to make sure they're consistent, especially in areas that are the same between volumes.

For example, reciprocity, when an Agreement State licensee comes across and goes into an

NRC space, they have to send in a letter for reciprocity. We want to make sure that it's consistent between the volumes of what they have to do to do this.

And finally, at the end, we'll bring in the rulemaking updates with the final publication.

As I said, we have received ACMUI recommendations. We received ten on October 8, 2015. We are looking at those comments to incorporate.

As was said this morning from Sophie Holiday, we will issue a memo explaining if there is any differences that the staff incorporates that are not fully incorporated or not incorporated the same way that it has been recommended or if no action was taken on that recommendation. We're going to explain why the staff made that determination.

One recommendation that was made was the comment period extension. The ACMUI recommended that NUREG-1556, Volume 9 have a longer public comment period than the other 1556 volumes because of the complication with medical use licenses.

I believe that it was recommended for 90 days. Working through it right now, the staff is recommending a 60-day public comment period.

This is double the amount of time that is allowed to other volumes. It was recognized this is a

complicated volume.

The ACMUI has provided, as I said, nine other recommendations and we are going through those with our working group and incorporating those.

And moving on to any questions?

VICE CHAIRMAN ZANZONICO: Pat Zanzonico.

I'm a little confused, I'm a little confused by this approach because, if I understand correctly, there will only be two reg guides published, one without the rulemaking section and with within a year of one another.

Because it says draft Volume 9 Guidance published and then it says below that then there's an arrow connecting the two lines where you'll publish a final version with the rulemaking changes incorporated.

DR. TAPP: So, the draft Volume 9 Guidance published will be published for public comment. It is not going to be published final.

VICE CHAIRMAN ZANZONICO: No, understood. But, even with that, it still seems confusing to, you know, perspective stakeholders to comment on what is essentially an incomplete version and then, within a year, comment on the final complete version.

DR. TAPP: The public has already had an opportunity to comment on the rulemaking version. We

did not want to confuse people by putting it back out.

As we're going the parallel paths, we wouldn't have to wait for all that to be finalized, wait for the Commission. It would add a large delay to our publication. So, we were doing it in parallel paths so we can issue the final publication as soon as after the final rulemaking is done.

The public has to have -- or we want to give the public a chance to comment on all changes. So, this was a pathway that would allow the public to see both the rulemaking changes as well as the non-rulemaking changes.

But, the public will have a chance to see both.

VICE CHAIRMAN ZANZONICO: I guess we agree to disagree --

DR. TAPP: But, I take your comment.

VICE CHAIRMAN ZANZONICO: -- in terms of this approach.

CHAIRMAN ALDERSON: Other questions or comments?

Dr. Langhorst?

MEMBER LANGHORST: Pat, you're right, it is very confusing.

And, I have been trying to think of how to

help in this effort, especially as you put out a draft of the non-rulemaking changes.

And, I wonder if maybe you can designate those parts that are involved in the rulemaking in some way to say, this was reviewed, this was updated in the rulemaking and point them in that direction so that they're not giving you feedback on stuff that isn't up to date with the rulemaking.

And, it is going to be confusing with the comments that you bring back, but I don't know how better to help.

I will say, and I think my licensing people at Region III know this, I love the NUREG-1556 series. And, it is very helpful to me as a radiation safety officer in developing licensing -- license amendments, license applications and so on.

And, I commend you for making things consistent and trying to make sure that if you have regulatory guidance that you keep it in one location so you only have to update that one and you reference it, and especially by hyperlinks is great. I know it's not the greatest for those who still have to look at paper, but at least I think that is the way to go.

And, I know it's a big effort and I really thank you all for all the work you're doing on it.

DR. TAPP: Thank you.

MEMBER LANGHORST: Thank you.

CHAIRMAN ALDERSON: Yes, Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Not to beat this horse to death, but my concern is that you're going to get a segment of users who are going to see the draft guidance and say, okay, this is the law of the land, this is what I'm going to follow and almost be completely unaware of the subsequent final publication.

I mean, this two-step approach, and I understand the rationale for doing it from a logistical point of view, but it seems almost destined to create problems among, you know, a segment, perhaps most of, you know, the user base.

DR. TAPP: I have just a quick response.

The staff is well aware that this could create confusion. We want to be as clear as possible when we issue this for public comment and we take the suggestions here as how to do that.

CHAIRMAN ALDERSON: Yes, Dr. Howe?

DR. HOWE: I think it's helpful to know that when she puts out her draft and it does not include any of the rulemaking, then it will pertain to the existing Part 35.

So, you won't have a draft that says, oh,

your training experience, you don't need an attestation anymore. It will still say you need an attestation.

Now, as soon as the rule is final, we'll have guidance to say you don't need the attestation anymore. That will come back together on the final NUREG and you will have to absolutely follow in Part 35.

But, on the draft, that'll be out before the final rule comes out. So, you won't be confusing people between what's in the existing regulations because it doesn't have any regulatory changes. It just has consistency.

VICE CHAIRMAN ZANZONICO: I'm already confused. The problem is the proximity in time. I mean, if I get a draft guidance and then six months later, you've got a second draft guidance, you know, if I were a more casual user, I wouldn't be expecting something revised that if the first draft guidance said you still needed attestation, I would continue indefinitely or I can foresee a number of users continuing to indefinitely based on that guidance.

DR. HOWE: And, one of the things that we had to kind of focus on was, what if we had -- we have Revision 2 out there now, right, that's the current one, Revision 2. This will be Revision 3.

Well, we were faced with Revision 3 coming

out and then within a very short period of time, maybe a month or two, Revision 4 coming at us.

And, we thought that was going to be a lot more confusing as to, well, why have you revised it twice in three months when it's taken you ten years before?

So, we're bringing these things up parallel with the idea, they will come together and will be one huge revision to Volume 9. Because, we think that's going to be, in the end, the clearest that -- what Volume 9 are you dealing with? I'm dealing with Revision 3. Okay, it's all in Revision 3. You don't confuse 3 and 4 because they're two or three months apart.

CHAIRMAN ALDERSON: Yes, Mr. Fuller:

MR. FULLER: Yes, this is Mike Fuller.

And, Dr. Zanzonico, just know that we feel your pain. This is not something that we're trying to pull on, you know, pull the wool over anybody's eyes.

Staff has struggled with this for several years. You know we've been in rulemaking for many years.

We have requirements that when we propose a rule, we publish a proposed rule. We must publish the draft guidance, which we did. And we got comments on that. That's part of the rulemaking process.

Then, and we keep talking about parallel

paths, we have an obligation to revise this guidance irrespective of the rulemaking. That's a fact of life. That's just we have to do that. It's not an option for us.

So, we have -- the staff has been put in a position of having to do two different things at the same time that involve NUREG-1556, Volume 9. Again, it's a fact of life.

Now, we are doing the best that we can to clarify for the various audiences, those folks that are interesting in having the guidance in response to the current rule and then those folks who are very much involved and interested in our new 10 CFR Part 35 rule.

Once, and I'm now repeating what everybody else has said, once we publish the final rule, once we get direction from the Commission to publish the final rule, shortly after that, all of that draft guidance that's contained in 1556 will be made final and that will feed into Katie's project and we'll publish it just one time as final.

So, again, you know, like I said, we feel your pain and we understand. We explained it as best that we can. When we publish the 1556, Volume 9 draft 3, for public comment, we will try to make this very, very clear for everyone involved.

But, it's, as I said, we are where we are and we are obligated to do both of these things which are different things. And, that's the best way I can describe it.

CHAIRMAN ALDERSON: Further comments?

Yes, Mr. Mattmuller?

MEMBER MATTMULLER: Would it be helpful, as I understand it, there's going to be one more chance for the public to comment on the draft, would it be helpful to have, maybe not this whole graph, but at least part of this to explain to the public, okay, you're commenting on this part of it here and that the new guidance relative to the new final rule has already been worked on?

So, just to help them keep the two processes separate.

DR. TAPP: That is a good comment and we'll look into that.

CHAIRMAN ALDERSON: We'll ask if anyone is on the line right now who's a member of the public who wants to comment about this issue? Is there anyone on the line that wishes to comment?

There are no such comments.

More comments from within the room here? Members of the ACMUI? I'm sorry, I missed somebody.

Yes, sir?

MR. MCMURTRAY: Hello. I'm Tony McMurtray. I'm the overall Senior Project Manager for the NUREG-1556 project. So, I've got all 21 volumes that I'm trying to work with Katie and others to move through.

I appreciate all the comments that we have here. As we've said, we'll work with our admin. We'll probably put up in the draft a comment section, maybe this time line or something specific for this.

We also have this issue with the Volume 13, Radiopharmaceuticals, because there's going to be language also in that volume that's going to come from the rulemaking that's going to come in.

Just as some background, some of the key things that we're trying to do with the overall NUREG-1556 series, we're putting security information in there to address the Part 35 rulemaking that happened for security and we're doing a lot of things with consistency and bringing all the volumes into a consistent standpoint.

We just -- if you want to look and see what some of this information looked like, we just issued for final report Industrial Radiography, Volume 2 last week. So, you can go on our public website and look at

that. You can see some of that standard information that's in there.

But, as Katie mentioned, things like Agreement State information, an update on the Agreement State map, reciprocity, all those sort of things, we've updated that, some of the things as far as electronic submittals. There's a lot of new information like that that we've added in.

So, we appreciate the comments and we'll work to try to clarify this both for Volume 9 and Volume 13 when we put those out.

CHAIRMAN ALDERSON: Thank you, Mr. McMurtray.

Are there questions for Mr. McMurtray?

MEMBER MATTMULLER: Just one quick comment.

I think if you could put this out there, then put a little red arrow to tell the public, you are here.

CHAIRMAN ALDERSON: Okay, that's a nice sound suggestion.

Thank you very much.

Other questions or comments about this topic?

Hearing none, thank you --

DR. TAPP: Thank you.

CHAIRMAN ALDERSON: -- Dr. Tapp.

I think that we're ready to go on to the next item on the agenda which is Sophie Holiday talking about the Committee Reporting Structure.

MS. HOLIDAY: Hello, again.

And, I think I'm going to up Donna-Beth and say, *this* is the most important presentation that you'll hear --

CHAIRMAN ALDERSON: We all say that.

MS. HOLIDAY: All year long.

So, today, I'm going to speak to you about what is the current reporting structure, talk about or give you your annual review. As I said earlier this afternoon, this is a recommendation from the Committee put forward for us to review your structure on an annual basis, talk about your meeting frequency and then open it up for discussion.

So, many of you are very familiar with this chart. You just saw it this morning in Dr. Alderson's presentation. This is simply just to say that you, the Committee, reports to Dan Collins who is the Director of the Division of Materials Safety, States, Tribal and Rulemaking Programs, which is within the Office of Nuclear Material Safety and Safeguards.

And, of course, our office, NMSS, falls under the purview of the Executive Director for Operations, Victor McCree, which some of you also got to meet after the meeting.

And then, the EDO relays staff's positions and things of that nature to the Commission.

The dotted line simply represent that each of these individuals, and I did not have a dotted line for the Director of MSTR, but this is not to say that the dotted line does not exist, it's simply to say that all of these individuals have an Open Door Policy, which simply means that, at any time you guys wish to come in and speak to them, you have that opportunity. You just have to arrange it with their secretaries.

And, lastly, that box at the bottom, MSEB, represents our branch, which Doug is the Branch Chief of - the Medical Safety and Events Assessment Branch.

Like I said last year, while it may seem like you report to me, you do not. Our branch just oversees and supports the day-to-day activities of the Committee.

So, in an annual review in September of 2012, the ACMUI reiterated their recommendation to have an annual review of your reporting structure. This is the sixth annual review that we have conducted since

then.

I think my best quote that I like to say comes from the ACMUI Bylaw Subcommittee Report in which Dr. Zanzonico presented the Committee with the option to continue reporting to our office, NMSS, or directly to the Commission.

And, in that report, it stated, verbatim, ''the working relationship between the NRC and ACMUI remains excellent. The reporting structure through NRC staff continues to function effectively and the associated logistical overhead associated with direct reporting to the Commission, e.g. the need for more frequent meetings, did not and does not now justify any change in the ACMUI's reporting structure.''

Comparatively, we have another federal advisory committee, the ACRS, Advisory Committee on Reactor Safeguards, this is actually one of their meeting rooms. And, they report directly to the Commission.

So, on an annual basis, this Committee reviews if you would like to be similar to ACRS and report directly to the Commission or continue reporting to staff or rather the management in NMSS.

So, we meet here at Headquarters twice a year in the spring and in the fall. Your spring

meetings are usually between March and April and your fall meetings are usually between September and October.

We hold ad hoc teleconferences on an as needed basis. That means approximately each year, we have between two to three teleconferences, although some years, you know, you may have less or you may have more. It just depends on what the need is.

So, at this time, I would like to open it up for discussion.

Is the Committee satisfied with continuing to report to NMSS or would you prefer to report directly to the Commission?

Are you agreeable to two in-person meetings or would you like more or would you like less?

What other changes would you like to see?

Thank you.

CHAIRMAN ALDERSON: Thank you, Ms. Holiday.

Now, those are three separate questions. I hope we can discuss them in three separate orders.

So, the first question was, does this -- is this ACMUI happy with its current reporting structure or would we prefer to report directly to the Commission?

So, let's try to address that single

question.

Mr. Costello?

MEMBER COSTELLO: I have a question about something the Chairman said today. And, the impression I got was, if we were working and reporting directly to the Commission, I'm sorry --

That the Chairman said if we were reporting to the Commission like ACRS is, you couldn't have people who are actively engaged as members appear, you'd wind up having people who are retired.

I don't know -- understand why that is, but if that is the case, then clearly we benefit by not reporting directly to the Commission because look at all the practical experience you're getting now.

But, is that true?

MS. HOLIDAY: I will paint the picture like this, ACMUI meets here twice a year. ACRS meets here ten times a year in-person.

And, your meetings are usually -- they're here for in-person full committee meetings as well as subcommittee meetings.

MEMBER COSTELLO: So, I gather that means that it's not required by law that they be retired, but no one here could give up that much time to come here ten times a year for meetings. And so, practically, it

has the effect of not being able to have people who are currently practitioners be able to do the work.

Thank you.

CHAIRMAN ALDERSON: Additional comments?

Yes, Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: I think we will recognize that the medical component of the NRC overall is a relatively small component and the concerns and knowledge of the Commission is -- that's a small portion of the overall concerns.

And so, if we, for whatever reason, decided it was advantageous to report directly to the Commission, we frankly would be dealing with individuals who have much less familiarity, much less knowledge, et cetera, et cetera, of all of the issues used in medical applications of byproduct materials.

And, I think we would spend a lot of our time explaining and re-explaining things and much less time productively in, frankly, discussing real issues.

So, I think given how the -- what the NRC does overall and how it's configured, I think we're far better off working through the staff than working directly with the Commission.

CHAIRMAN ALDERSON: Other comments on this particular question?

The first two comments both favor continuing our current reporting structure. Are there any people who would speak against that particular idea?

Hearing none, I think we have resolved that question. We would like to continue with the current structure.

I believe the second question had to do with two meetings a year at the Headquarters. So, that issue is, we currently meet twice a year and is the ACMUI pleased with that? Thinks that a good frequency of meetings or feel that we should meet at some other frequency?

So, those who might wish to comment on that, please do so.

MEMBER COSTELLO: I think two is the right number.

CHAIRMAN ALDERSON: Mr. Costello thinks two is the right number.

Several people are nodding their heads in agreement at this point.

Dr. Zanzonico, would you like to comment?

VICE CHAIRMAN ZANZONICO: Our meeting is ending at 1:00, so we don't even need two full days for this meeting. So, two is enough and three we'd just be sitting around staring at each other. I think it's the

right number of meetings.

CHAIRMAN ALDERSON: So, it seems that the consensus of the Committee is that the two meetings a year is the correct amount.

Am I hearing anyone speak against that? No, so we agree that two meetings a year would be fine.

And, remind me of what the third point was?

MS. HOLIDAY: Are there any other changes that you would like to see?

CHAIRMAN ALDERSON: Right, a more open question. Are there any other changes you would like to see?

So, if anyone would like to see any, please -- Dr. Ennis?

MEMBER ENNIS: We talked, I guess, earlier this morning about that we need to get more feedback from -- I apologize.

We talked this morning, there were comments that the Commission made this morning, I believe, that getting more feedback from NRC staff to ACMUI with why, what was the thinking in adopting or not adopting particular recommendations.

And, along those lines, and consistent with kind of the overarching theme here, is there -- ought there be a time and place for NRC to give feedback to

ACMUI in general about their performance, if you will, I think we're doing a great job, but what would you like to see better or worse or strengths and weaknesses, is that something that is done? Should be done?

MS. HOLIDAY: So, actually, you may be familiar, Dr. Ennis, and many of the members are, every two years, staff writes a paper to the Commission which is our biennial evaluation of the Committee.

So, when I had you guys forms, there were questions that you had to answer about the Committee's interactions, staffs interaction with the Committee, things of that nature.

On the other side, staff also has to evaluate the Committee.

So, both the staff's position and the Committee's position or evaluation is included in that Commission paper. And, we, too, agree with you that we are very satisfied with the Committee.

CHAIRMAN ALDERSON: Mr. Costello?

MEMBER COSTELLO: I have one issue maybe to refer to the table. I believe that years ago, that there was no cardiologist on the ACMUI because back then, that was all done by nuclear medicine physicians and now we have the benefit of nuclear cardiologists.

We've had recent discussions, a lot of

recent discussions, about alpha and beta emitters and the role of medical oncologists.

Were there any reason to consider including the oncologist, someone who's not a radiation oncologist, but a medical oncologist as a member of the Committee? Is that someone who can contribute to our discussion we have about the, you know, the alpha and beta emitters, is that a viewpoint that we're missing with our current membership?

CHAIRMAN ALDERSON: So, I think it's appropriate for the ACMUI to comment on that question before we go to Dr. Langhorst and her next question.

So, would people like to comment on that issue? Should we have a medical oncologist on the ACMUI?

Dr. Ennis?

MEMBER ENNIS: A lot of what we're doing is not oncological related. So, a lot of their expertise would not be particular helpful and they may not be interested. But, also not necessarily needed.

I think that having radiation oncologists who bring the oncology background and the radiation background really suffices, I think, unless people feel otherwise, for that knowledge.

And, obviously, we can always have guests

come as we and just see, to bear -- give us their expertise for those certain things where needed.

CHAIRMAN ALDERSON: Yes.

Yes, Dr. Dilsizian?

MEMBER DILSIZIAN: This is nuclear cardiology, but nuclear cardiology I think they do nine million procedures per year in this country. So, it's not just a cardiology specialty, it's actually works with ionizing radiation and they have expertise in it.

And, wherein, oncology, ionizing radiation is really not part of their training and there's a subspecialty, certification board of ASNC which is NRC recognized. So, it's not the same.

CHAIRMAN ALDERSON: Other comments to this particular question?

Dr. Suh and then Dr. Palestro?

MEMBER SUH: So, I also concur with the two previous individuals. I think the value-added for having medical oncology as part of the ACMUI would be very limited because I think their scope and knowledge would be very limited.

And also, on the current Committee, it's radiation oncology. I think the oncology perspective would be reserved.

CHAIRMAN ALDERSON: Dr. Palestro?

MEMBER PALESTRO: I would agree with Dr. Suh and the previous comments.

In addition to that, I think that with the open forums that we have, there's also the opportunity for oncologists and whoever else wanted to contribute and offer information or even use radiopharmaceuticals, that's more than ample.

But, I would also point that we don't have any physician on the Board, nor do I think it's necessary, to have an endocrinologist on the Board to address issues of radiation pertaining matters and they even have a certification board for that.

CHAIRMAN ALDERSON: Would anyone else like to comment on this question?

Mr. Costello, I think the consensus of those commenting is that we do not need a medical oncologist on this Committee, but could call one if we needed their expertise.

MEMBER COSTELLO: Thank you.

CHAIRMAN ALDERSON: Good.

Are there any other comments on this question of other things the Committee -- oh, yes, Dr. Langhorst was going to make a comment.

MEMBER LANGHORST: Thank you very much.

I know one of the things that we have

discussed during this kind of annual review and so on is the level of medical use or medical team support and the challenges that they face as far as funding and being able to do their jobs.

That's always a concern. We've already heard a few instances where they've not been able to work on things we presented to them because they don't have the resources to do so.

I think the extensive time of getting Part 35 rulemaking through is hard to believe. And, there's no -- you saw on what Sophie went through this morning that there are things that are pending the next Part 35 rulemaking.

Well, I'm pretty sure most of us won't even be alive when that starts.

So, I just want -- I'm sorry, I'm talking about the Committee here.

I just want to say that the funding for the medical team and, if we go back to last fall and the report on abnormal occurrences, they're all medical. I mean, there's very few, but that's not the focus that NRC puts on things.

So, I just wanted to make mention of that. And, we think that there should be a little more funding for the medical team.

CHAIRMAN ALDERSON: Thank you.

Other -- yes, Dr. Ennis?

MEMBER ENNIS: I think that's very interested, I hadn't thought of that, but if there were more staff like to Part 35, would that -- is it realistic to think that if there had been more staff that could have been done in significantly less time?

MR. BOLLOCK: In regards to that, the current Part 35 rule, I don't know that that would necessarily have sped it up that much. I'm sure every, you know, every bit of resource helps.

And, we have a lot of our staff helped with the Part 35 working group. But, there is a lot of other factors that, internal, external factors, and changing factors over the past ten years that delayed the rule, not so much our staff resource.

And, I think my staff can attest that when it came down for the time for that working group to get back together and go over the comments and work on it, we put -- we shift effort and we've been able to do it fairly well. We've been flexible enough.

You know, but as anything, any organization, we have our challenges with resources. As just look around the room, you may see that Ashley Cockerham is no longer with us. So, right now, we're

looking at filling her position. So, right now, we're one staff down.

Actually, for a number of months, we're two staff down because we also fill other roles in the Agency and I have another member of the medical team helping out the division. And, that just happens.

So, as far as more people on the -- I think as long as we are fully staffed to what we're supposed to have, we can get a lot of work done. Unfortunately, that's not always the case and we weren't able to get to the patient intervention, we weren't able to get to that in the past year with the rule and with patient release project and five or six working groups for 35.1000 guidance.

So, but, you know, we appreciate the endorsement to get more resources. I wish, you know, I wish we had more resources. I wish I had more money for -- to get out to the -- more societies and send more staff out to the processional societies and, you know, train everybody as much as possible.

Unfortunately, you know, we are in an -- our current budgetary environment is we are shrinking. I think we'll still be able to do everything we need to do, I'm confident of that. But, we're not going to be able to expand on that, unfortunately, not in the near

future.

CHAIRMAN ALDERSON: Ms. Weil?

MEMBER WEIL: Lest I put myself in the unenviable place of trying to make more work for the team, it would be useful for us, I think, as a Committee, to hear more reports from the working groups.

We have only half a day tomorrow and we would do our work better if we understood the context in which it all fits into place.

I know that you do stuff that we don't hear about much or certainly not every time. And, while I'm sure you don't want us meddling in everything you do, I think we could be more productive if we had the bigger picture.

CHAIRMAN ALDERSON: Mr. Costello?

MEMBER COSTELLO: Kind of in support of what Sue had to say. While the, and the reason why I think it's important is you provide as many resources as they can to the medical side of the program.

While medical -- the NRC program is a relative small part of what they do. If you think of the number of people in America who are actually affected by what we do, it's probably almost anyone you know knows someone who's either having a diagnostic test, having a treatment or knows someone who is.

Probably, you're talking hundreds of millions of people who are affected one way or another by what we do.

And, all due respect to the other side of the house here, I think the routine impact that they may have on those hundreds of millions of people may not be so immediate as what we do here.

So, I'm just tooting our own horn here. What we do here is very important. What your team does is very important. And, I rather hate the idea of having to have cuts at all.

CHAIRMAN ALDERSON: Are there any other comments on this topic?

Well, thank you, and I believe that terminates our discussion of new issues.

And, we'll now move on to Katie Tapp, again, who will talk to us about the update on Yttrium-90 Microspheres Brachytherapy Licensing Guidance.

DR. TAPP: Thank you.

I'm now going to discuss the update to the Yttrium-90 Microsphere Brachytherapy Licensing Guidance.

What I'm going to go over today is an outline of what was changed in the Revision 9 that was recently issued. It was issued on February 12, 2016 as

final.

In addition, I'm going to discuss the NRC and Agreement State working groups consideration for a potential future updates of what we're actually going to be looking at for the possibly Revision 10.

First, with the Revision 9 changes, the first change, large change to this licensing guidance, was to specifically exclude reporting of medical events that are due to static or emergent patient conditions.

In addition, we're also excluding events that are caused by shunting when shunting was evaluated prior to treatment in accordance with manufacturers' procedures.

This was a -- these both were recommendations from the ACMUI and they were incorporated into this revision.

With the removal of the reporting of the events with shunting, the shunting dose and activity is no longer required to be documents on the written directive.

Additional training or additional changes is to the training experience section where we are allowing interventional radiologists certified by the American Osteopathic Board of Radiology to be deemed status for authorized user as well as this guidance is

an updated format which includes a Table of Contents and easier to use to be able to use.

And this is something that's going to be done for all of our Part 35.1000 licensing guidances in the future.

Now, I'm going to shift gears to future considerations.

We wanted to get that last revision out quickly because we knew those were important updates. I believe all the updates are important, but those were some that the ACMUI recommended that we get out and to review and issue as soon as we possibly could.

Now, we are going on and doing future considerations to look as see if there's more revisions necessary for this document.

I'll go over each of these considerations separately.

The first one is on long-lived impurities. In 2007, the NRC was notified that there were long-lived impurities in the Yttrium-90 microspheres, both in TheraSpheres and SIR-Spheres. These impurities are created by the manufacturing process themselves.

The working group is considering potential updates to this section because we're hearing that there might not be impurities in the TheraSpheres -- in some

of the microspheres.

The working group is considering this update to either the section of the guidance document itself or to the IN document, the Information Notice that was issued in 2007.

The next consideration is to the autopsy and cremation. This was a topic that was discussed by Dr. Zanzonico at a previous ACMUI meeting.

The microspheres, when they're injected into a patient, they become trapped in the patient in the capillary beds. These are permanent.

As you know, the Yttrium-90 has a short half-life and will probably decay away. But, there is considerations to the long-lived impurities. These are something to be considered then during autopsy and cremation upon the death of a patient.

The working group is considering if information needs to be added to the licensing guidance to provide guidance to individuals in regards to autopsy and cremation.

Finally, we're considering the training and experience section. This was not open in the last revision, but we are opening this now to look at it closer.

In particular, to the pathways that we

allow -- that we grant authorized users.

What we're looking at, specifically, is the two pathways that interventional radiologists become authorized users.

The first pathway is to receive their three clinical hands on cases under the supervision of an authorized user.

The second pathway is to have a representative from the manufacturer come out and to complete their three clinical hands on experience with the manufacturer there.

The working group is evaluating as if that manufacturer pathway is still necessary. That pathway was added because there was not as many authorized users for Yttrium-90 when it first started.

As we are aware that this procedure is growing, there are becoming more authorized users, so we're evaluating if that pathway is still necessary.

The schedule of this, the working group is working currently on looking at these considerations and if we decide that a new revision is necessary, the draft is expected here in the spring.

This would then allow for the ACMUI to look at the draft and provide a comment period as well as an Agreement State review. And then, we expect to issue

this in the summer.

Leave that open to the now discussion.

CHAIRMAN ALDERSON: Questions on this update?

Dr. Langhorst?

MEMBER LANGHORST: I have a little more generic question. On licensing guidance, typically you don't open that up for any public comment, is that correct?

DR. TAPP: That is correct.

MEMBER LANGHORST: I feel that's a lost opportunity. I mean, it wouldn't necessarily need a long public comment period, but in making these various revisions, well, I think that would be helpful. Just my opinion.

CHAIRMAN ALDERSON: Is anyone else on the ACMUI like to extend that discussion with a further opinion?

It appears not.

MS. HOLIDAY: Dr. Alderson?

CHAIRMAN ALDERSON: Yes, Sophie?

MS. HOLIDAY: This is Sophie.

If I could, Dr. Langhorst, while we don't necessarily post licensing guidance documents for public comment, on our NRC's medical use licensee

toolkit, where these licensing guidance documents are housed, there is a statement there that says, at any time, the medical community or members of the public, something along those lines, have the option or the ability to inform NRC if changes are necessary for guidance.

That is the reason why Revision 9 for the Y-90 guidance has been issued. And, it's also the reason why the ACMUI had a Radioactive Seed Localization Subcommittee formed because staff received comments from a few members of the public regarding the recentness or the outdatedness, rather, of the RSL guidance.

So, there are opportunities for that to happen at any time members of the public can do so.

Thank you.

CHAIRMAN ALDERSON: Thank you for that clarification.

Yes, Dr. Langhorst?

MEMBER LANGHORST: And, I appreciate that. But, it's a little bit different if you're saying, okay, here's what we're planning to update and if you can get some feedback on that immediately rather than trying to develop the justification for redoing a licensing guidance, that's much more onerous for an RSO to propose

or others in a licensee than it is to at least have some opportunity of input, at least to see it and maybe even go through their ACMUI representative, I don't know.

But, it is a little frustrating in that way, from my perspective.

CHAIRMAN ALDERSON: Dr. Palestro?

MEMBER PALESTRO: I have a question, I guess, it's really directed toward the staff. Why aren't they posted for public comment?

DR. TAPP: Sure. These are licensing guidances for the license reviewers for evaluating modalities that are regulated under 10 CFR 35.1000.

35.1000 modalities are emergent technologies that we're trying -- that we use under this pathway under licensing guidance for the review because they are coming out faster than our rulemaking process can adapt the medical use.

In the regulations, when we do regulations, we have to have a public comment period. As you guys are well aware, once we do public comment period, that does add extra time. So, that would add extra time to these modalities when we're trying to get out guidance that can be used quickly for emerging technologies that are moving very quickly.

CHAIRMAN ALDERSON: Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Yes, I fully second what Sue was suggesting. I mean, these are very complicated procedures and to generate a licensing guidance for any purpose without the input of the practitioners, the people doing them, is almost certain to generate an inadequate document.

I mean, you really need the input of people who do these procedures. There are so many points and steps where something can go wrong and interpret or misinterpret it as a medical event.

I mean, as Sue said, it's a real missed opportunity not to solicit the input of the practitioners in this area.

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: I can certainly understand the hesitation to just open it up for public comment and then you get all these comments and you have address each of them.

What is, and I don't know how you do this because I know there's rules and requirements that don't allow you to, but to have a few people who do these things on your working group would be wonderful and would have an opportunity of bringing the medical community into the regulatory development of these things and give you that valuable perspective.

Because, you guys don't have physicians working at Agreement States or at the NRC.

And so, I don't know if there's any possibility of being able to do that. I'm sure there probably isn't and I'm not saying that you have to then have an ACMUI member on there, because heaven knows, you guys don't want to have a third meeting at all.

So, that's our frustration because these are being done in what appears to be a vacuum.

CHAIRMAN ALDERSON: So, these interesting comments are on the spectrum of communications which we talked this morning to the Commission about.

I'm not saying by making that comment that means this is one beyond the top of the priority list, maybe it would, maybe it wouldn't, but it's on that communication spectrum.

And, you're right, that if you had an open website, well, there'd be a lot of comments that would be perhaps hard to field and it might take, you know, somebody assigned to that area.

But, in this day of social media and people communicating with each other so quickly all the time, a number of organizations are literally developing groups who communicate this way, as one of the things they do to communicate with their constituencies.

So, it isn't beyond the realm of the discussions we might have about communication that we might be thinking about whether the NRC might eventually want to do something on that spectrum.

Ouhib, you have a comment?

MR. OUHIB: Yes.

So, my question to you is, what you're going to be working on is based on what and who's feedback exactly?

DR. TAPP: The original revision, Revision 9, was actually based on recommendations from a Subcommittee from the ACMUI which was then the ACMUI's recommendations.

The changes there were all ACMUI recommendations. There was no additional ones.

But, with the other ones, some of these are from members of the public or manufacturers have submitted comments to the NRC as well as the cremation and autopsy section was an ACMUI presentation in the past that the staff took up.

So, we do communicate with groups and manufacturers when we do these working groups. But, we don't have standard process to make them open for public comment in draft form. We do discuss changes and things we're looking at with practitioners.

MR. OUHIB: Yes, to simplify the process, would it be beneficial to approach professional organizations, basically, and they will be able to perhaps guide you a little bit in that. And, I mean like ASTRO, AAPM and so on and so forth instead of, if you cannot go to the public, perhaps you can go to these professional organizations and they will be able to provide you some valuable feedback.

MS. HOLIDAY: Dr. Alderson, this is Sophie. If I could weigh in at this time?

CHAIRMAN ALDERSON: Please.

MS. HOLIDAY: I'd like to respond to Dr. Langhorst and Mr. Ouhib. I'll go with Mr. Ouhib first because I don't want to lose my memory.

So, as far as going to the professional societies, we still treat the professional societies as members of the public. If you are not an NRC employee, you're considered the public, or another federal agency, you're grouped under as a member of the public.

As far as getting feedback from the medical community and who participates on these working groups, these working groups really, in the most recent years, or for the past five, six years, maybe more than that, these 35.1000 guidance documents have been developed by a joint working group.

By joint, I mean members from both NRC staff and from the Agreement States.

As we've heard over and over again, we have 37 Agreement States which make up over 87 percent of the medical use licensees in the country.

So, the beauty of our working groups is that we get both NRC's perspective as well as the Agreement States' license reviewers. And, I will pick on my co-chair who's here from my Icon Working Group, Mr. Eric Perry works for the Kentucky Department for Public Health. So, he's also on my working group as a non-NRC staff person.

The working groups also have the ability to reach into our resources, and that is the ACMUI. The ACMUI serves as both an advisory committee, but you can also serve as medical consultants.

Our working groups have been able to use members on the ACMUI when we need that expertise.

For example, when the ViewRay Licensing Guidance was developed, my working group did reach out to Dr. Suh as a gamma stereotactic radiosurgery radiation oncologist for his expertise.

Likewise, the Y-90 Microspheres Working Group was able to rely on the Y-90 ACMUI Subcommittee and their recommendations. And, that Subcommittee was

comprised of many of the physicians that represent the medical community that administers this procedure.

So, we always have that ability to incorporate the advice and the expertise and the knowledge from the medical community.

While we don't post it for public comment, these documents are considered pre-decisional, but because the ACMUI are NRC special government employees, that's why we are able to give them to you for your review and your comment before we move it forward.

Likewise, we also send the guidance in the draft form to the NRC regions where our license reviewers are, as well as the Agreement States for their review and comments as well.

So, not only are we getting comments from NRC staff, we're getting them from Agreement States staff and the ACMUI.

Thank you.

CHAIRMAN ALDERSON: Thank you.

Yes, Dr. Howe?

DR. HOWE: I think one of the things to remember is that we're talking about emerging technologies. And so, while some of them that you were talking about now, Yttrium microspheres have been here for a number of years.

We also have others coming down the pike that have not been used yet. So, we don't have the professional societies out there with the experience for it. We don't have the medical use licensees out there with experience for it.

But, there's a tremendous push to get them out so they can have these. So, many cases where these emerging technologies, we have to come up with a regulatory framework. If they can get out and get into the medical community where they can be used, we try to go with the fastest route we can and that is guidance on our website versus a much more structured guidance document like the 1556 series where we really have to go through the full rulemaking kind of a process.

So, that's one reason you don't see things necessarily in the beginning. But, as Sophie has indicated, once we put them up on the website, and you guys do get a chance to look at it, but once we put them up on the website, they're not in concrete. They are considered now working documents that anyone can respond to and you guys can look at again.

So, that's one reason we try to get them up quickly. The idea that maybe we aren't all inclusive but we're trying to get them up as fast as we can so that the medical community really has access to it.

CHAIRMAN ALDERSON: So, Dr. Howe, when you put guidance up on the website, is there something on the website that says if you, you being the person who's looking at the site, have comments on this guidance and then some sort of hotlink where they can click and then send a message or is it just out there for them to read?

DR. HOWE: We do have, I think Sophie talked about it earlier, we have a statement up on the website that they can make comments at any time and submit them to us.

CHAIRMAN ALDERSON: Okay.

DR. HOWE: I think, do we have -- Sophie, do we have like an email that we bring them to medical questions?

Yes, so we have a system set up so they can bring them in to us and then we constantly monitor this email system --

CHAIRMAN ALDERSON: That's good.

DR. HOWE: -- to try and answer questions.

CHAIRMAN ALDERSON: Good, okay.

Mr. Fuller?

MR. FULLER: Yes, just one more thought about this.

I'm reminded that the Yttrium-90 microsphere update Revision 9 as it is that Katie's been

talking to us about, I just think back, you know, what kind of prompted this.

You know, it was the ACMUI as the result of reviewing, and I kind of thought of this as a real success story, they ACMUI was reviewing the medical event information that Dr. Howe had reported out on and there was some good discussion about is this, you know, do we have the right medical event definition and so forth for Yttrium-90 microspheres?

This Committee formed a Subcommittee. Dr. Guiberteau headed that up. And, I remember when he made his presentation on what changes were needed to this guidance.

He said, you know, I'm not an expert so I reached out to my colleagues who are. And, he brought a very, very strong compelling argument with lots and lots of information that the staff was able to then use as our basis for why we realized that changes were appropriate.

And, that's what we got. I mean, we got what we felt like and this Committee felt like was excellent information from the medical community and from the actual experts in the field.

And so, I kind of see this as a, again, sort of a success story.

We are challenged when we realize that, as regulatory agency, we have certain tools in our toolboxes to actually develop these regulatory tools or these regulatory -- or these ways in this new framework for emerging medical technologies.

We are very, very interested in doing this quickly and in a very agile and nimble way. We are able to update things without going into rulemaking and so forth.

So, adding another layer, and I know it doesn't sound like much, but if you really think about what we would have to, we would have to do everything that we're doing now and then we would add another step of publishing it for public comment, receiving those comments, forming a working group, looking at each and every one of those comments, deciding which ones were reasonable and which ones were maybe outside of the scope.

And then, bringing that back to the ACMUI for your review of our responses to those comments.

I mean, it goes against the original objective of 35.1000, in my opinion, of being very, very responsive to the needs of the medical community.

So, I'll just leave it at that.

CHAIRMAN ALDERSON: Thank you, Mr. Fuller.

We have a comment from the audience.

MS. FAIROBENT: Yes, Lynne Fairobent with the American Association of Physicists in Medicine.

While I appreciate the concept of what was started with 35.1000 way back in 2002 when the rule was originally drafted, the intent was never that we would regulate forever by guidance under 35.1000.

Nothing has been moved out of 35.1000 and, remember, it is guidance and the Agreement States do not have to comply with it.

And, while I recognize it was an attempt to expeditiously address emerging technologies, I'm not so sure it's been the success that we all thought it might be.

And, I agree with Dr. Langhorst, I believe it was who said, with just posting of the guidance, there is not opportunity for the public input.

And, yes, there is a link and there is discussion, but if one looks at doing rulemaking in a timely fashion in accordance with NRC documentation, I would argue that over ten years to do a Part 35 rulemaking is not timely regulation.

CHAIRMAN ALDERSON: Thank you, Ms. Fairobent.

Do we have other comments from the

Committee?

MEMBER COSTELLO: I have a question.

CHAIRMAN ALDERSON: Oh, you have a question? Frank Costello has a question.

MEMBER COSTELLO: I appreciate what you did with the Subcommittee's recommendations. I think you're very proud of what you did, actually.

I do have a question, though. When you talked about shunting, you're excluding shunting when shunting's evaluated as part of treatment, I think, then you say in accordance with the manufacturer's procedure. Well, there are only two manufacturers. Right?

Are those, as an inspection regulator, are those procedures unambiguous and easy to come by?

DR. TAPP: They are. The procedures do have -- the manufacturers do have their procedures on their website. So, if you're talking about like package inserts, they are publically available documents. They describe the shunting evaluation procedures that they recommend that be followed.

So, inspectors can see those on publically available websites and we can provide those, too.

MEMBER COSTELLO: So, they're expecting them, the licensees, to follow what the manufacturers

recommend for evaluating shunting to lung or whatever.

And, if they're not doing that, if they're not doing that and they have shunting to the lung or they have shunting to the GI tract, then that might be a problem.

DR. TAPP: Yes. And, the procedures are generalized for this procedure for the pre-treatment shunting evaluation. I think we've heard of it before is the pre-treatment where they inject the tech-99m MAA and evaluate that by imaging or the angiograms with the contrast.

They are in both manufacturer procedures, they are only about a paragraph long discussing that.

MEMBER COSTELLO: But, there is something there?

DR. TAPP: Yes.

MEMBER COSTELLO: That if anything happens, I can go on the manufacturer's website and look up that procedure and then say, Mr. Licensee, did you follow this?

DR. TAPP: Yes.

MEMBER COSTELLO: Okay, thank you.

CHAIRMAN ALDERSON: Do have other questions or comments?

VICE CHAIRMAN ZANZONICO: I just have a

couple of specific questions that I might be misunderstanding some things.

But, we said training and experience allowed interventional radiologists certified, but I mean that's in addition to allow training and experience for ABR certified individuals who have the AU designation. This is in addition to that?

DR. TAPP: This is in addition to what was there before for ABR. It is interventional radiologists subspecialty as well.

VICE CHAIRMAN ZANZONICO: And, further on when you discussed training and experience, you said current license guidance, et cetera, et cetera, provided by either an AU Pathway 1 or the manufacturer.

But, isn't the manufacturer -- does that mean a non-AU who received -- I mean, because an 'or' implies that a non-AU who receives a manufacturer training could be effectively an AU for this procedure. Is that the intent?

DR. TAPP: This is the current guidance that's out there right now is it is an AU or a manufacturer representative. It is not specified that that manufacturer representative had to be an AU in the current guidance.

That is what we are looking at evaluating.

VICE CHAIRMAN ZANZONICO: Somehow that doesn't seem right.

MEMBER COSTELLO: I remember that the manufacturer's representative doesn't -- isn't even a physician.

DR. TAPP: That is correct. That is how it's currently --

VICE CHAIRMAN ZANZONICO: So that means a non-AU who went through the manufacturer's training could administer these?

DR. TAPP: They do have to have training beforehand and they do have to, for this pathway, they do have to be an interventional radiologist in training or certified. But, yes, that is correct, the three cases would be under supervision from a manufacturer representative, it is not specified they have to be a physician.

VICE CHAIRMAN ZANZONICO: Something just doesn't seem right.

MEMBER COSTELLO: In fact, they're often not a physician, they're an evaluator.

DR. TAPP: Yes. That's what --

MEMBER COSTELLO: I mean, know who these people are and they're often not physicians.

DR. TAPP: This is why the working group

has received comments and we are evaluating this pathway to see if it's still necessary because there are a lot more authorized users.

This is something the staff is evaluating. It was not yet a recommendation from the ACMUI.

CHAIRMAN ALDERSON: Dr. Metter?

MEMBER METTER: I have a question.

So, let's say you have an authorized user who's -- sorry.

So, let's say you have a nuclear medicine physician who's an authorized user for Y-90 microspheres and you have an interventional radiologist who does the arteriogram and then administers the Y-90 but is not an authorized user, but it's under the licensee of the nuclear medicine physician. Can that interventional radiologist be the prompter for the three therapies for their training?

DR. TAPP: They're not an AU?

MEMBER METTER: Correct.

DR. TAPP: Under current guidance, if they're following this guidance, that does not sound like they could be the AU doing -- or they could be the supervisor for these three cases.

MEMBER METTER: Okay.

DR. TAPP: It would have be a nuclear

medicine AU.

MEMBER METTER: Okay, thank you.

CHAIRMAN ALDERSON: Are there other questions about this report?

Hearing none, Mr. Bollock, I think that we've reached the end of today's sessions. Did you have anything you'd like to say in closing?

MR. BOLLOCK: No, just thank you all and I guess Sophie has something before we all leave.

CHAIRMAN ALDERSON: We have a couple of logistical issues, too, that I'd like to --

MS. HOLIDAY: A couple of logistical issues.

CHAIRMAN ALDERSON: -- bring out, but they're not, you know -- pardon me.

MS. HOLIDAY: I'd just like to remind everybody, I know it's a little bit confusing on the agenda, we are returning for our open session at 8:00 a.m. tomorrow, not 8:30 a.m. So, I'm asking staff and ACMUI members to arrive by 7:45 so we can start on time.

Make sure to take your name badges off as you don't run off with them and forget them tomorrow.

CHAIRMAN ALDERSON: So, we begin at 8:00 a.m. tomorrow?

MS. HOLIDAY: 8:00 a.m. tomorrow.

CHAIRMAN ALDERSON: Yes.

And, so I just -- I turned the microphone off because we're --

So, just a couple of issues that I -- the more serious one that I want to bring up is I'm personally very interested in and hope all of you are, too, in what Ms. Houseman's going to, you know, talk to us about tomorrow.

And, as Ms. Houseman -- and she's worked hard in preparing some slides. It should be a great discussion.

Now, when -- so, I'm a little concerned that it's at 1:00 to 2:00 p.m. Has that been moved up?

MS. HOLIDAY: It should be 12:00 to 1:00.

CHAIRMAN ALDERSON: Good, it is 12:00 to 1:00. Pat and I were both confused about it, but it's 12:00 to 1:00, that's very good because I think a lot of people, not me in this case, but a lot of people plan to get away and their air transportation on the basis of a 1:00 p.m. close or approximately that.

And, this is an important session. This may well engender a number of questions and discussion. So, I just wanted to make sure, so we're starting that at noon, that's excellent.

MS. HOLIDAY: Yes, I think you were looking

at an old version.

CHAIRMAN ALDERSON: Well, it may be, there's several versions laying around here on the table.

The other issue is, you know, very logistical and more social than anything else and that is, that usually, this evening after we part, we usually congregate downstairs at the hotel for an hour or so.

And, if people -- pardon me? Or more, or many more, so, for those, so it's now ten minutes to five, so what do you say, 5:30 downstairs? Does that seem reasonable?

So, to get there and grab a big table and save some chairs and then we'll all sort of gather around.

Okay, well, that's great.

Thanks everybody, I think it's been a great day.

(Whereupon, the above-entitled matter went off the record at 4:49 p.m.)