Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Meeting of the Advisory Committee on the Medical Uses of Isotopes

Docket Number: (n/a)

Location: Rockville, Maryland

Date: Thursday, October 6, 2016

Work Order No.: NRC-2647 Pages 1-219

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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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FALL 2016 MEETING

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THURSDAY,

OCTOBER 6, 2016

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The meeting was convened in Room T-02B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:00 a.m., Philip O. Alderson, M.D., ACMUI Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

PAT B. ZANZONICO, Ph.D., Vice Chairman

FRANCIS M. COSTELLO*, Agreement State Representative

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

SUSAN M. LANGHORST, Ph.D., Radiation Safety Officer

DARLENE F. METTER, M.D., Diagnostic Radiologist

MICHAEL D. O'HARA, Ph.D., FDA Representative

CHRISTOPHER J. PALESTRO, M.D., Nuclear Medicine Physician

JOHN H. SUH, M.D., Radiation Oncologist

LAURA M. WEIL, Patients' Rights Advocate

NON-VOTING: RICHARD GREEN

NON-VOTING: ZOUBIR OUHIB*

*via telephone

NRC STAFF PRESENT:

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

PAMELA HENDERSON, Deputy Director, Division of Material Safety, State, Tribal and Rulemaking Programs (MSTR)

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

CLIFF DOUTT, NRR/DLR/RASB

MICHAEL FULLER, NMSS/MSTR/MSEB

VINCENT HOLAHAN, Ph.D., NMSS/MSTR

ESTHER HOUSEMAN, OGC/GCLR/RMR

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

ANGELA MCINTOSH, NMSS/MSTR/MSEB

GRETCHEN RIVERA-CAPELLA, NMSS/MSTR/MSEB

REANN SHANE, COMM/OCMJB

MICHELLE SMETHERS, NMSS/MSTR/MSEB

KATHERINE TAPP, Ph.D., NMSS/MSTR/MSEB

TORRE TAYLOR, NMSS/MSTR/RPMB

JENNY WEIL, OCA

MEMBERS OF THE PUBLIC PRESENT:

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

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

ASHLEY COCKERHAM, Sirtex

ROBERT DANSEREAU, New York State Department of Health

WILLIAM DAVIDSON, University of Pennsylvania

ADAM DICKER, American Society for Radiation Oncology (ASTRO)

JENNIFER ELEE, Conference of Radiation Control Program Directors (CRCPD)

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

SANDRA GABRIEL, International Atomic Energy Agency

KSENIJA KAPETANOVIC, American Society for Radiation Oncology (ASTRO)

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

JOSEPH MACE, Florida Cancer Specialists

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

SHAHIN NASSIR KHANI, Walter Reed National Military Medical Center

ERIC PERRY, Kentucky Department for Public Health

MICHAEL PETERS, American College of Radiology

KAREN SHEEHAN, Fox Chase Cancer Center

MICHAEL SHEETZ, University of Pittsburgh

DAVID SMITH, Medstar Georgetown University Hospital

BRUCE THOMADSEN, Center for the Assessment of Radiological Sciences (CARS)

CINDY TOMLINSON, American Society for Radiation Oncology

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P R O C E E D I N G S

8:07 a.m.

MR. BOLLOCK: Good morning, everyone. We'll begin now that we have everybody seated. As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this fall meeting of the Advisory Committee on Medical Uses of Isotopes. My name is Doug Bollock. I'm the Branch Chief of the Medical Safety and Events Assessment Branch and I've been designated as the Federal Officer for this Advisory Committee in accordance with 10 CFR Part 7.11.

Present today is the Alternate Designated Federal Officer, Sophie Holiday, our ACMUI coordinator.

This announced meeting of the committee 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 and reported by others. This meeting was announced in the August 3, 2016 edition of the Federal Register, Volume 81, page 51216 through 51217.

The purpose of the committee is to advise the staff on issues and questions that arise in the

medical use of by-product 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 values their opinions.

I request that whenever possible we try to reach consensus on the various issues that will be discussed 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 roll call of the ACMUI members participating today. Dr. Phil Alderson, Chair.

CHAIRMAN ALDERSON: Here.

MR. BOLLOCK: Thank you. Dr. Pat Zanzonico.

VICE CHAIR ZANZONICO: Here.

MR. BOLLOCK: Thank you. Mr. Frank Costello, are you joining us via the phone?

MEMBER COSTELLO: I am here now.

MR. BOLLOCK: Thank you, Frank. Dr. Vasken Dilsizian.

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Thank you. Dr. Ronald Ennis.

MEMBER ENNIS: Here.

MR. BOLLOCK: Thank you. Dr. Sue Langhorst.

MEMBER LANGHORST: Here.

MR. BOLLOCK: Thank you. Dr. Darlene Metter.

MEMBER METTER: Here.

MR. BOLLOCK: Thank you. Dr. Michael O'Hara.

MEMBER O'HARA: Here.

MR. BOLLOCK: Thank you. Dr. Christopher Palestro.

MEMBER PALESTRO: Here.

MR. BOLLOCK: Thank you. Dr. John Suh.

MEMBER SUH: Here.

MR. BOLLOCK: Thank you. And Ms. Laura Weil.

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you. Also at the table we have Mr. Richard Green.

MR. GREEN: Here.

MR. BOLLOCK: Thank you. And on the phone we may have Mr. Zoubir Ouhib joining us. Zoubir, have you joined us on the phone? Unfortunately, Mr. Ouhib is in Florida, so we may or may not hear from him given

the current situation in Florida.

Mr. Zoubir Ouhib has been selected as the ACMUI Therapy Medical Physicist and Mr. Richard Green has been selected as ACMUI Nuclear Pharmacist. Both Mr. Ouhib and Mr. Green are pending security clearances, but may participate in the meeting. However, they do not have voting rights.

I'd also like to add that this meeting is being webcast, so other individuals may be watching on line. We have a bridge line available and that phone number is 888-831-8979. The pass code to access the bridge line is 9959317 followed by the # 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 the handouts and agenda for this

meeting are available on the NRC's public website.

At this time, I ask that everyone who is on the call who is not speaking to place their phones on mute. If you don't have the capability to mute your phone, please press *6 to utilize the conference line, mute, and un-mute functions.

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

MR. COLLINS: Thank you, Doug. Hopefully, everybody can hear me. Thank you to all the committee members for your time and for traveling out here to attend this meeting. You've got a couple of very important topics on the agenda today. I'll talk a little bit more about it in a minute, but just by way of some general information for you, since the last time you met in the spring, the Office of NMSS has a new Office Director. Mr. Marc Dapas reported to that position in late July. Mr. Dapas has extensive experience in power reactor regulation, security and in nuclear materials. He was formerly -- his last job he was the Regional Administrator for NRC Region IV out of Dallas. Prior to that he was the Deputy Office Director in the Office of Nuclear Security and

Response. Prior to that he was the Deputy Regional Administrator in Region I and prior to that he was the Division Director for the Division of Nuclear Material Safety in Region III. So he's brought experience, familiar with both the medical and commercial and industrial applications of nuclear materials from both the safety and security viewpoint. So he's no stranger to the topics that we're going to be discussing today. And it's nice to have him. So I just wanted to let you know that.

And then secondly, just kind of if you're following the press, you may be aware that security of radioactive materials is in the press again. There was a GAO report issued in mid-July which covered another undercover operation that they had conducted in 2015 in which they had posed as a fictitious company and submitted applications to two Agreement States and one NRC region for license to obtain a Category 3 well logging source. In two of the attempts they were unsuccessful in obtaining a license that was from one Agreement State and from the NRC region that they applied to. In the third case, another Agreement State, they were successful in obtaining a license. They then used that license and got a commitment from a source supplier to provide a Category 3 well logging

source. After they had that commitment, they modified a copy of the license to change the source, make, and model number that they were approved for and were able to get a commitment from another supplier for another Category 3 source.

In total, they never did take possession of the material, but if they had, the two sources that they would have obtained would have aggregated to a Category 2 quantity of material. So NRC has been working diligently over the past almost year now to take a look at the vulnerabilities that were exposed by that undercover operation, both in terms of our licensing process, but also looking at ways to address the accountability aspect of Category 3.

We're expecting to get some further direction from the Commission to direct the staff to do a further reassessment of our regulatory infrastructure for accountability for Category 3 sources. So that's just going to continue to be something that we're working on.

And we do have a Commission meeting coming up on October 27th, that's going to be talking about the staff's assessment of the adequacy of 10 CFR Part 37 which is security for Category 1 and 2 quantities of material but there's some overlap with the security

for Category 3 sources. So something that's still in the works and that you should probably be aware of.

Moving on into the ACMUI specific topics, we did send the Part 35 rule up to the Commission in June. And so that's still under Commission consideration. We don't have a direction or decision from the Commission yet.

Towards the end of June, on June 24th, ACMUI held a teleconference to discuss the draft ACMUI Subcommittee report for revisions to the radioactive seed localization guidance and the committee did unanimously approve the report at the June meeting. That guidance has not been issued yet. It's with OMB right now for a Congressional Review Act review.

During that same teleconference, we also heard a presentation from NRC staff regarding the potential rulemaking to expand the financial assurance requirements to include Category 1 and 2 radioactive sealed sources tracked in the national source tracking system. There's a staff recommendation that just went up to the Commission last week related to that. So we don't have a decision from the Commission yet.

ACMUI held a teleconference in August on August 10th to discuss the subcommittee's report and comments on the draft ACMUI germanium-68/gallium-68

generator licensing guidance. The staff issued the licensing guidance last week on September 28th and so we thank the working group or actually the working group thanks ACMUI rather for their review and comments on the draft guidance. And Dr. Tapp will be discussing this more tomorrow morning in her presentation.

On July 29th of this year, a memorandum was provided to the U.S. Nuclear Regulatory Commission Regional Administrators that delegate to them the authority to grant specific license exemptions from the decommissioning funding plan requirements for medical germanium-68 and gallium-68 generators and we'll also hear more on that tomorrow from Dr. Daibes.

Tomorrow, we'll also hear a presentation from Dr. Palestro related to his subcommittee's efforts and possible revisions to the training and experience requirements for all modalities under 10 CFR Part 35. And immediately following his presentation, we'll hear a presentation from Spectrum Pharmaceuticals regarding the training and experience requirements related to authorized users of alpha and beta emitters.

Dr. Dilsizian will give a presentation on ACMUI's comments on the draft RadioGenix, moly-99, technetium-99 generator system, which I guess is the NorthStar Medical Radioisotopes LLC, 10 CFR 35.1000

licensing guidance.

And Dr. Metter, we're looking forward to your presentation on ACMUI's comments on the draft revision 10 of the NRC licensing guidance on yttrium-90 microsphere, brachytherapy sources and devices.

And lastly, I'd like to mention that while Dr. Langhorst is not scheduled to rotate off of ACMUI until September of next year, the solicitation for nominations for the Radiation Safety Officer position on ACMUI was published in the Federal Register on August 30, 2016 and any nominations are due by the end of October, October 31st of this year. And with that, Dr. Alderson, I'll turn the meeting back over to you.

CHAIRMAN ALDERSON: Thank you very much. I think we're ready to move to old business and Michelle Smethers who has joined the group will speak to us.

MS. SMETHERS: Good morning. It's nice to be here with you today. I'm new to this, so I'm still learning how to use the microphone, but I am Michelle Smethers and it's good to be here with you today.

The next portion of our agenda that I will go over is a familiar piece that we do at each meeting. At every meeting we go over old business which recapped all of the recommendations and actions put forth by the committee and/or staff and noting any changes.

With that said, much of what you heard today will be very similar to our previous meeting in March.

So getting started, for the 2007 chart, all of the items that are listed as open are included in the current Part 35 rulemaking and open and delayed means they will be considered in future rulemaking.

Sophie is going to have to help me out with moving these forward.

Moving on to 2008, again all of these items that are listed as open are included in the current Part 35 rulemaking and again open and delayed means they will be considered in future rulemaking.

For 2009, we have two items on the chart, and again both of these items are also included in the current Part 35 rulemaking.

Moving to 2010, oh, there is no 2010. Please note then that in 2010 -- please note that 2010 is not included because all recommendations and actions were closed previously.

Continuing on to 2011, items 11, 13, 14, and 15 are included in the current Part 35 rulemaking. Going back to item 1, item 1 and 16 had to do with the patient release criteria. Both these are pending because there are two patient release efforts going on

at the NRC, one in the Office of Research and one in the Office of Nuclear Material Safety and Safeguards.

Moving to the end for item 32, Dr. Oxenberg will provide an update tomorrow morning on the proposed revision to the Abnormal Occurrence Criteria Policy Statement.

We did go over item 6, the last one is the indefinite open action item for the committee to review its reporting structure on an annual basis. The next review of this item will be next spring meeting.

Moving on to 2012, all items for 2012 were closed or addressed in the March 2016 spring meeting.

So moving on to 2013, items 1 through 13 are part of the current Part 35 rulemaking. Item 21 pertains to the Germanium-68/Gallium-68 generator where the ACMUI recommended relief from the decommissioning funding plan requirements. Staff issued a memorandum to the NRC regions in July 2016 that grants them the authority to issue licensing exemptions from the decommissioning funding plan. Requirements for Germanium-68 provided that certain conditions are met. You will hear from Dr. Daibes regarding this topic tomorrow.

I would like to make a motion to close this item since staff issued the exemption memo in July 2016.

CHAIRMAN ALDERSON: A motion has been made. Is there further discussion?

MEMBER LANGHORST: Don't we have to make a motion?

CHAIRMAN ALDERSON: Do we have to make the motion?

MS. SMETHERS: I request that we make a motion.

MEMBER LANGHORST: I'll so move. Sue Langhorst.

CHAIRMAN ALDERSON: Is there a second? All in favor. Opposed. Abstentions.

(Committee votes.)

That passes unanimously.

Back to you.

MS. SMETHERS: Thank you. Please note that item 25 will be removed after this meeting, since it was closed last meeting and NRC staff sent up the rule to the Commission for votes.

We'll move on to 2014. Again, item 6 pertains to the same Germanium-68/Gallium-68 topic. Again, I would like to request that we make a motion to close this item since staff issued the decommissioning funding plan exemption memo in July 2016.

MEMBER LANGHORST: Sue Langhorst, I so move.

CHAIRMAN ALDERSON: Second. Further discussion? Hearing none, all in favor? Any opposed? Any abstained?

(Committee votes.)

None, passes unanimously. Back to you.

MS. SMETHERS: Thank you. This now closes the 2014 recommendation and action chart.

Moving on to 2015, item 7 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. You will hear more on this from Dr. Oxenberg.

For items 12 through 15, we will hear a presentation later today from Mr. Fuller in response to the committee's remarks on the term "patient intervention."

For item 18, item 18 deals with the comments and recommendations provided by the Radioactive Seed Localization Subcommittee. The ACMUI recommended that the individual who implants the source for radioactive seed localization procedures can do so under the supervision of an authorized user. Staff accepted this recommendation in its revision of

the radioactive seed localization guidance. However, this is not final yet and is pending congressional review.

For item 22, like item 7, item 22 has to do with the NRC's Abnormal Occurrence Criteria Policy Statement. As I mentioned earlier, we will hear a presentation from Dr. Oxenberg tomorrow regarding an update on the Abnormal Occurrence Criteria Policy Statement.

Yes?

MEMBER LANGHORST: You said on item 18 it was awaiting congressional review and do you mean Commission review?

MR. BOLLOCK: No, it's Congressional Review Act review.

MEMBER LANGHORST: Oh, okay. I wondered why Congress was going to review it. Okay.

MR. BOLLOCK: No, and Dan spoke on that one. OMB is reviewing for Congressional Review Act. So if they make a determination that it needs to be reviewed by Congress, then it will go to Congress.

MEMBER LANGHORST: Got it. Thank you.

MR. BOLLOCK: We don't foresee that.

MEMBER LANGHORST: Thank you.

MS. SMETHERS: Thank you, Dr. Langhorst.

Okay. Item 23, is that where we were? Okay. Item 23, the ACMUI endorsed the NUREG-1556, Volume 9 Subcommittee Report. We have left this item open because as you are aware, the NUREG-1556, Volume 9 has not been finalized yet. I was notified by Dr. Tapp that they will let the ACMUI know when it is issued for public comment.

Moving on to 2016. Items 1 through 15 all deal with the Part 35 Rulemaking Subcommittee Report that had the recommendation related to the draft final rule. Staff transmitted a response memorandum to the ACMUI on August 2, 2016 which conveys staff's reasons for partially accepting or not accepting the committee's recommendation. The Part 35 rulemaking package is sitting with the Commission for vote as Dan mentioned. We'll hear an update later today from Ms. Torre Taylor.

Item 16, for item 16, we will hear from Dr. Palestro tomorrow for an update on the work done by the new Training and Experience for All Modalities Subcommittee.

Item 17 through 19 are closed, but remain on the list pending recommendations from the Training and Experience for All Modalities Subcommittee.

Item 20 is the commitment by the NRC to

provide data to the ACMUI for medical events reported over a five-year span for trending purposes. Ms. Holiday provided this data to the ACMUI for the time period of fiscal years 2010 through 2015 on October 3, 2016. Consequently, I would like to request that this action be closed.

CHAIRMAN ALDERSON: Is there a motion to close this out?

VICE CHAIR ZANZONICO: So moved.

CHAIRMAN ALDERSON: And second?

MEMBER LANGHORST: Second.

CHAIRMAN ALDERSON: Further discussion? Hearing none, all in favor. Any abstaining? Any opposed?

(Committee votes.)

Hearing none, unanimously approved.

MS. SMETHERS: Thank you. And please note going forward, staff will continue adding to the list provided by Ms. Holiday.

CHAIRMAN ALDERSON: I would just like to make a comment that I thought the summary was excellent. It was clear. It really summarized the trends very well, so thank you to Ms. Holiday for providing this information.

MS. SMETHERS: Thank you. Item 21

pertains to the formation of the Medical Event Reporting and Impact on Safety Culture Subcommittee. The subcommittee will report at the Spring 2017 meeting.

For item 22, item 22 is an NRC action to provide the draft final 35.1000 licensing guidance for the Leksell Gamma Knife Perfexion and Leksell Gamma Knife Icon to the committee. Ms. Holiday provided the draft final guidance to the ACMUI on April 19, 2016. The final guidance was issued on May 25, 2016. And consequently, I would like to request that this action item be closed.

CHAIRMAN ALDERSON: Would someone like to move in that regard?

MEMBER LANGHORST: So moved.

CHAIRMAN ALDERSON: Second. Discussion? Hearing none, all in favor. Opposed? Abstained?

(Committee votes.)

It unanimously passed. Thank you.

MS. SMETHERS: Thank you. Item 23 was an NRC action to provide the ACMUI with the total number of medical use licensees within the United States. Ms. Holiday provided the requested information on March 18, 2016. Again, I would like to request that this item be closed.

VICE CHAIR ZANZONICO: So moved.

CHAIRMAN ALDERSON: And a second?

MEMBER DILSIZIAN: Second.

CHAIRMAN ALDERSON: Discussion? All in favor? Opposed? Abstaining?

(Committee votes.)

It passes unanimously. Thank you.

MS. SMETHERS: Thank you. Item 24 was an ACMUI recommendation to reach out to professional organizations to encourage interactions and communications between these organizations, the NRC, and the ACMUI. We will hear a presentation from Dr. Alderson tomorrow reporting on these outreach efforts by the ACMUI.

Would you like to close this item at this time or keep it on the list for now?

CHAIRMAN ALDERSON: I'd like to keep it on the list.

MS. SMETHERS: Okay. Thank you. Item 25 was an ACMUI action to hold the Fall 2016 ACMUI meeting. And since we are all here today and we are holding this meeting today and tomorrow, October 6th and 7th, I would like to request that we close this item.

CHAIRMAN ALDERSON: Yes, and I assume since you're all here, one of you who is here can make

such a motion.

MEMBER METTER: So moved.

MEMBER DILSIZIAN: Second.

CHAIRMAN ALDERSON: All in favor? None opposed or abstaining.

(Committee votes.)

Please carry on.

MS. SMETHERS: Thank you. For items 26 through 30, management approved the radioactive seed localization guidance in August 2016, but it is pending a review against the Congressional Review Act. Once OMB has made the determination that the guidance is not considered a major rule, it will be distributed to the regions, Agreement States, and ACMUI. Staff will also post it on the medical tool kit and send an announcement out on the medical list serve.

For items 31 through 37, staff issued the Germanium-68/Gallium-68 Eckert & Ziegler GalliaPharm guidance on September 28, 2016. Dr. Tapp will discuss this further on Friday.

This concludes my portion of old business. Are there any questions or comments?

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: Yes. Some things were in red, some things in black and I was confused whether

it had any meaning at all.

MS. SMETHERS: I asked about this as well because I worked on this with Sophie Holiday and she said that red items are things that have changed since last meeting. Is that correct? Do you want to add anything to that, Sophie?

MS. HOLIDAY: That is correct. So red text indicates anything, any actions that may have changed whether we accepted, did not accept, if an action was closed or moved to open and delayed.

MEMBER LANGHORST: So the closed items were closed last time, but they remain on the list because they're black.

MS. HOLIDAY: They may have been closed last time or an action may have occurred between the March meeting and this meeting that would have resulted in a closed action.

MEMBER LANGHORST: Okay. And I wanted to make one comment. I really appreciate the size of the font because it used to be so teeny tiny to read and I really thank you.

MS. SMETHERS: That was all Sophie.

MS. HOLIDAY: If I may before we adjourn from the old business portion, it did not make it as a change on the old business chart at the time because

these were printed September 16th, but as Ms. Smethers indicated, the Germanium/Gallium-68 GalliaPharm Eckert & Ziegler generator licensing guidance was issued on September 28th. I would like to request if the ACMUI would like to make a motion to close those items on the list related to the Germanium/Gallium-68 Subcommittee's recommendation.

CHAIRMAN ALDERSON: Is there a motion to that effect?

MEMBER LANGHORST: So moved.

CHAIRMAN ALDERSON: And second?

MEMBER COSTELLO: Second.

CHAIRMAN ALDERSON: Further discussion? Hearing none, all in favor? Opposed? Abstaining?

(Committee votes.)

It passes. Thank you. Thank you, Ms. Smethers for your report.

MS. SMETHERS: Thank you.

CHAIRMAN ALDERSON: This moves us to the open forum where the floor is open for the ACMUI to identify medical topics of interest for further discussion. Is there any -- yes?

MEMBER LANGHORST: Sue Langhorst, yes, thank you. I just wanted to echo Mr. Collins' comments on the Category 3 sources. This is something that

medical licensees have to keep a close eye on because this will impact the need to track more sources. And Senator Schumer has sent a letter to the Chairman calling for a ban on licensing any new Category 3 sources. I mean so the Commission has a lot of pressure on it in regard to this.

Right now, the discussion is tracking those sources in the National Source Tracking System, the NSTS. It hasn't been mentioned about putting it into Part 37 where you have to have additional security. What that impacts for medical licensees is primarily the HDR sources in radiation oncology. It would be a lot more effort in the security end of things.

Now all of the ploys to get licensing have been for industrial gauges for those -- oh, gosh -- help me with that, what's the licensees -- they're the -- yes, the well loggers and so on. There's a lot more effort to get a medical clinic up and running and I don't think a storefront would pass as a medical clinic. But still, this has big impact. So I just -- I think that's something that we need to pay close attention to and know what's happening in the NRC world about this topic.

CHAIRMAN ALDERSON: Good. Other comments on that? I think, yes, Ron Ennis.

MEMBER ENNIS: We may have addressed this

a little bit the last time, but there are efforts in other parts of the Federal Government, like the Department of Energy.

I think we may have touched on this a little last time, but there is an effort underway in the Department of Energy to also introduce a variety of regulations about radioactive sources for security concerns, but I and other medical specialists are quite concerned about the impact it might have particularly in the area of oncology and Gamma Knife and HDR, but depending on where the line is drawn and a concern that it could not make it illegal to have such sources, but create such barriers as to essentially de facto remove those sources from medical practice. It's well-known to this subcommittee that this committee that these are providing really critical treatments for people and I think we need to be aware of it and maybe we need to express something as a committee about our concern on the potential impact on cancer care.

CHAIRMAN ALDERSON: Thank you, Dr. Ennis. Would anyone like to follow up that comment or have another comment in that regard?

John Suh.

MEMBER SUH: I also just want to echo what Ron just mentioned. The modalities that we use for a

high dose rate brachytherapy as well as gamma knife radiosurgery are really important and proper treatment of cancer patients for a lot of different diseases. So I also think it's important as a subcommittee we follow this very carefully because I believe it would be detrimental to patient care if those modalities were very difficult to utilize because of regulations.

CHAIRMAN ALDERSON: Those are excellent comments. I'd like to keep those in mind. I don't think we're going to stop right now and form a new ad hoc subcommittee to look at this, but it is an issue that we could consider in the future if this continues to be out there.

I also appreciate Dr. Langhorst bringing it forward because I think if you can go back to when I started on the committee, I asked about the security of various radiation sources used in medicine and with the suggestion that this committee know more about them, be informed, be talking about and engaged in that issue. So I think with this further interest now that we may wish to do so.

There's a comment here in the room, yes?

MS. FAIROBENT: Thank you, Dr. Alderson. Lynne Fairobent with the American Association of Physicists in Medicine. I just wanted to mention that

the community at large is very much actively involved in this issue and has created a new group on source security working group with many organizations that are members of that. There is a 12 member steering committee and AAPM is one of the steering committee members.

We have been on the Hill recently and we'll continue to do so in an education and outreach to Hill staffers. It was mentioned that there are or have been pieces of legislation that have been promulgated and we have been working actively to keep them from going forward, but also should something go forward to have it be appropriately reflected.

But I also did want to mention as a take-off on the press articles that was written, I don't know how many of you watch TV, and this goes to Sue's comments that -- and I totally agree -- that we've been fortunate, it's a little harder to stand up a storefront hospital or medical facility than it is a storefront licensee to receive industrial sources. But NCIS LA, their opening season issue this year involved the theft of several cesium chloride blood irradiators for dirty bombs. If you have not seen that episode, you might want to look at it. All of this publicity does not help our case.

I firmly believe, as does AAPM, that we are using radioactive materials safely and securely in medical applications and that they are actually critical to patient care in the overall scheme of things. But we cannot afford to lower our guard, shall we say, on watching what is going on and being proactive and not simply reactive every time an article appears in the paper. Thank you, Dr. Alderson.

CHAIRMAN ALDERSON: Thank you, Ms. Fairobent. I think that that was an excellent comment and I think overall we've got to establish a balance in the committee to look for that balance between availability for medical needs and safety and security for the nation. So we'll clearly be revisiting this topic.

Any other comments at this time? All right. We'll move on then, if there's no other comments. This is still the open forum.

Yes, Pat Zanzonico.

VICE CHAIR ZANZONICO: Yes, there's two issues I'd like to bring to the committee's attention for those of you who may not be aware of it, but recently the Nuclear Medicine Technology Certification Board, which is the national board which professionally certifies nuclear medicine technologists, are creating

a special competency area in radiation safety and it will have a certifying exam.

And I was recently at their meeting formulating the curriculum and drafting questions for that exam. And the intent is not to have any regulatory significance attached to this new certification. Their intention is not to create a subcategory of technologists, RSOs, so to speak. That's what they're saying publicly. I frankly find it hard to believe that that's not the ultimate intent, but their public stance is that that's not the intent.

What it is designed to do is recognize the reality, frankly, that in small practices and in private offices often it is the nuclear medicine technologist who performs the radiation safety tasks, wipe tests, so forth and so on. Of course, under the direction of typically the AU RSO and the thinking is that a technologist who had the certification would be more employable by having demonstrated expertise in this area, again, not to large hospitals, not to major medical centers where there's a radiation safety staff, but again, rather to private practices, small offices, even small community hospitals where there may not be that sort of support.

And as I said, it's the medical AU who is

listed as the RSO and so they would have to document this competency. And it would not just be for radioactive materials. It extends into radiation safety generally for radiographic sources, so forth and so on. So that is moving forward.

There seems to be a lot of support and a lot of interest among the nuclear medicine technology community in this competency because again, it does look like it would enhance and I imagine it will, their employability. So that's where that stands.

CHAIRMAN ALDERSON: One clarification point, Dr. Zanzonico, if I heard this correctly and this is the issue to clarify, you just said that the nuclear medicine technologists were going to be involved with the safety of radiation sources that are not radionuclide sources?

VICE CHAIR ZANZONICO: Well, they would -- in a practice, for example, where there might be PET/CT, there might be radiation generating machines.

CHAIRMAN ALDERSON: Such as CT?

VICE CHAIR ZANZONICO: Right, not just radioactive sources. The nuclear medicine technologists who had this competency or were granted this competency could do this while the certification board would also have to demonstrate competency in

those areas. So it's not strictly for radioactive materials and the curriculum and the exam will include material on non-radioactive source radiation safety issues.

CHAIRMAN ALDERSON: Thank you. That point is clarified. Thank you.

MEMBER DILSIZIAN: It's extremely important and I'm actually surprised that this is not even part of their training and certification to begin with. I would think that any nuclear medicine technologist should be aware of radiation safety issues, wipe testing and all -- not the CT portion, but all the others. So not only do I think this is important, but I think that it should actually be included in their training, not in separate certification. I think everybody should have it.

VICE CHAIR ZANZONICO: Agreed. And I think the notion is that this is to create a recognized competency area. It's an issue of marketability and employability.

There is a component in the general nuclear medicine technologist certification on radiation safety and related issues. I think this to formalize it, to recognize it, to expand it, but certainly that is part of their training.

CHAIRMAN ALDERSON: Yes, Dr. Palestro.

MEMBER PALESTRO: I actually have two comments. One is -- I think it's an excellent idea and I think it's not only good for marketability, I think it's good for radiation safety and patient safety.

My question is individuals who already are certified, can they go back and take an examination that will add this competency to their certification or an additional certification?

VICE CHAIR ZANZONICO: I'm not speaking for the NMTCB. I'm not part of that organization. I was just enlisted to help draft a curriculum and questions. But that is my understanding that in fact, an individual would first have to be certified by a nuclear medicine technology board before they become eligible for this additional certification. And it would include an in-residence requirement as well.

So in other words, they would have to have an AU RSO or an equivalent individual attest to the fact that they've been involved, I believe, for at least one year in radiation safety related activities. So yes, not only would existing certified techs be eligible, that would be a requirement for this additional competency.

MEMBER PALESTRO: So this is a separate

examination?

VICE CHAIR ZANZONICO: It's a separate examination.

MEMBER PALESTRO: Thank you.

CHAIRMAN ALDERSON: Yes, Mr. Green.

MR. GREEN: I think this is a worthwhile endeavor. My concern is that the NMTCB takes appropriate measures to make sure it's in the educational materials, as candidates take this course work, that they understand that they are becoming skilled and knowledgeable in assisting the RSO in health physics and radiation safety functions, but this does not grant them an authorized user status where they can independently make choices and decisions without the guidance and direction of the RSO.

VICE CHAIR ZANZONICO: Right, and as I have said, they've been very explicit in stating that NMTCB be very explicit in stating this is not a pathway to become recognized to act as an RSO. Again, that's what they're stating and hopefully, they'll stick to that. But I have a suspicion that as this moves forward that may become an effort on their part, but that's not the case at the moment. They would not be RSOs. They would not be listed on -- or licensed as RSOs, and so forth and so on.

CHAIRMAN ALDERSON: Further comments on this issue? Yes, Dr. Ennis.

MEMBER ENNIS: I guess, too, just kind of for informational purposes, is there an effort then on the board, whoever does their basic training, to incorporate this level just into the initial training so that this becomes maybe not necessary in the long run?

VICE CHAIR ZANZONICO: Again, I'm not speaking for the Board, but my impression is that at least in the initial roll out of this certification, and it's something brand new, that would not be the case. Now that may just be a logistical issue because they have obviously a large number of currently certified techs in the field, so they're not going to go back and retake the entire training. But I think the intention is that that would not be the case. In other words, they would take their normal training. They would take the normal or general nuclear medicine technology certification and then subsequently take this exam.

Now being eligible for the exam, as I said, has a residency requirement, one year working in the field, but it doesn't have a didactic training requirement so that once a tech is certified and working

in the field, presumably there is an AU or AU RSO who would attest their length of experience in that area. Then they can just sit for the exam without any additional didactic training.

MEMBER ENNIS: The question was the inclusion of nonradioactive source training, I'm not sure what's the rationale for that?

VICE CHAIR ZANZONICO: I think it's in the spirit of recognizing that in certain types of situations, like private offices, there may be multiple modalities involving radiation. And again, the RSO would be the position AU, but the individuals -- sort of the boots on the ground who would be implementing a lot of the regulatory compliance and that would include, for example, CT, doing certain measurements on that and so forth -- might be a technologist.

I think the nuclear medicine tech certification board sort of wants to state their claim that their constituency is often the individuals doing those safety checks beyond those for radioactive materials. I was a little surprised myself when I first saw how the broad scope of what they were aiming at, but that's their intent.

Again, since it doesn't have any legal standing or regulatory standing at this point, rather,

and you know, the Certification Board is a self-governing body, they can do what they want. They can make the rules and that's what they're doing at the moment.

MEMBER ENNIS: Does that reflect the reality on the ground that such technologists are doing CT, QA, things like that?

VICE CHAIR ZANZONICO: You know, I raised that question when I was at this recent meeting, because that's not my experience at all. And my experience may be skewed because I'm at a large academic medical center.

We have a large radiation safety group and medical physics group and there are sort of subspecialists for the different modalities, but according to the folks on the board, that is a reality that in certain small community settings, private offices and so forth, that is often a tech who -- a nuclear medicine tech who is doing these sorts of things beyond radioactive material.

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: Sue Langhorst. I think it also recognizes the fusion technologies and forgive me, Dr. Zanzonico, if you've already said that, but the PET/CT, there's always a question well, it's PET/CT

who's doing the CT and the CT measurements can be done under the authority of a qualified expert, but the techs may be doing those measurements and then it's reviewed by that qualified expert, so kind of a similar situation as rad material and RSOs.

VICE CHAIR ZANZONICO: That's a very good point and that was my inference that the reason this competency certification was extending beyond radioactive materials was because of multi-modality, not just PET/CT, but MR/CT also. But they're also including fluoroscopy, interventional radiology and even MRI and safety aspects of that. So it's a very broadly aimed competency certification at this point.

CHAIRMAN ALDERSON: I would just state that although it is of interest, obviously, to our panelists that such an idea is out there. It relates to safety which is something that we're engaged with. The ACMUI is, in fact, engaged with radionuclide safety, so the fact that this political action, it may in fact be a political action, it's extending beyond that realm, although of interest, it probably isn't in the core interest of this particular committee.

There's someone at the microphone. Thank you very much.

MS. BLANKENSHIP: Hi, Dr. Blankenship,

Bette Blankenship, AAPM, a physicist also an RSO. And I just wanted to comment to the group that we do have nuclear medicine technologists that work in a hybrid setting whether it's PET/CT or SPECT/CT and they are currently doing the CT testing, the quality assurance for those pieces of equipment, although they don't routinely do stand alone CT. They do get -- can be granted by their state -- to be a CT technologist on a hybrid device, so they have expanded their role. So I could see the importance of them wanting to have an understanding of the safety implications of working with that device, so they have just by nature of their work experience have been kind of thrust into a new environment for themselves. So I think it's a great idea, too. So thank you so much.

CHAIRMAN ALDERSON: Thanks very much. Good comment. Thank you. Are there further comments on this subject?

VICE CHAIR ZANZONICO: Again, I think what the board is thinking of and appropriately so, as a number of people have said, is that often the nuclear medicine technologists in reality are addressing and to some extent responsible for some of these safety-related issues. And this is a mechanism for formalizing that and recognizing it. But I think

that's the motivation for this at the moment.

CHAIRMAN ALDERSON: Good. The floor is open for other items. Dr. Zanzonico.

VICE CHAIR ZANZONICO: So this is a completely separate item and very recently at Sloan Kettering one of the new nursing leaders at the institution is a real advocate for breast feeding and has asked us to review and, if necessary, revise guidance on breast feeding, cessation of breast feeding, so forth and so on among patients receiving radioactive materials. There's all sorts of guidance included in the regulatory guides on cessation of breast feeding with administration of different radioactive materials.

And the issue has come up is should a recommendation be created for discontinuing breast feeding in advance of receiving a radioactive material. Apparently, because of the stimulation of lactation, there can be an increase deposition of radioactive materials in breast milk in women who are actively breast feeding. And so to reduce that uptake and presumably reduce any radiogenic risk associated with that uptake, there's now a question of whether there should be a recommendation to discontinue breast feeding for some period of time prior to the

administration of radioactive materials -- of the order of several weeks perhaps.

So that's not included at the moment in any of our institutional guidance and I don't see it in any regulatory guidance and I wonder if that's an issue that we should perhaps address.

CHAIRMAN ALDERSON: I think that is a very interesting subject to raise. We're in the open forum which is a relatively limited time period and this is not a subject that you just raised that can be discussed effectively in a very limited amount of time. So I'm going to ask you to set that aside and we'll think about bringing that back on to a future agenda or later in the meeting.

And I think at this time if there's no other questions we should move on to the medical event forum which is a major portion of our morning meeting. And Dr. Langhorst has agreed to introduce this segment. She helped organize to introduce this segment and give us a lead as we get started. Dr. Langhorst.

MEMBER LANGHORST: Thank you. As our panelists come up to the front, I just wanted to remind the committee that at last meeting, Dr. Alderson formed a subcommittee, the Medical Event Reporting and Safety Culture Impact Subcommittee. We haven't come up with

a catchy title yet on that, but that's what it is. And just to remind you, our charge is to explore the impact of medical event reporting and its impact on self-reporting safety culture, identify potential ways to improve the effectiveness of self-reporting in support of a culture of safety, and suggest ways to share medical event reports and lessons learned with the medical community to promote safety.

And so our subcommittee felt like it would be nice to have in attendance the groups that had reported to the committee, it's been a couple years now, who have event reporting systems that they have people reporting on.

And we've asked our panels to address these questions. How has your event reporting system grown? How do you share your results and with whom? Do you include near-miss reports? What do you think is the most important thing you have learned to date? What do your participants think of the feedback they receive? And what can ACMUI and NRC learn from your event reporting system?

Well, I want to thank the panelists that we have to help talk about this. Dr. Adam Dicker is here to present the ASTRO system. Ms. Jennifer Elee is here to talk about the CRCPD system. Dr. Bruce

Thomadsen is on the phone. He'll be talking about his system known as CARS. And Dr. Sandy Gabriel is on the phone. I hope those both are on the phone. She'll be speaking about the IAEA system.

And I will -- let's see, I guess Dr. Dicker will be the first one to present and so I'll let you take it away. Thank you.

DR. DICKER: Thank you, good morning. Just for those who are present with the help of Ms. Holiday, we are using the revised document. So it's my pleasure to present what we've learned from the RO-ILS system. I'm going to talk about where we've been, where we are, and where we're going.

I just want to first start out by what makes a smarter team. It's not intelligence. It's not IQ. I would contend in the RO-ILS system, there's been a lot of research by groups at MIT, Carnegie-Mellon talking about the subject and it boils down to three things. If you have three components for a team, you'll outperform other teams in problem solving. So it's about emotional intelligence of the team. It's about making sure that someone does not overtake the others and dominate the conversation. And the last part is having women. If you don't have women on your team, you're dead.

(Laughter.)

So this is incontrovertible. There's an updated paper in Science about this. There's a book, Smarter, Faster, Better. This is incontrovertible. And I'm contending the RO-ILS system is not the smartest, but is trying to get smarter.

Okay, this is the only medical specialty sponsored instant learning system for radiation oncology. It's a joint partnership with ASTRO and AAPM. It does receive some industry support. So the goal is really to have an environment which is safe, where people can share information in a non-punitive way, and that we can then bring it back to the community. I mean the community in the greatest collective sense of the word.

So as you know, this works under AAHRQ. There's a specific Patient Safety Act that prevents medical litigation and other types of lawyers from finding out about this stuff. We've been in existence for two years. We have over 224 institutions. We have 2300 submitted reports. We've issued seven quarterly reports and in the remaining time, I'm going to show you a little bit of our data mining and the examples that we've observed through this data mining and thematically what we've disseminated and I'll tell you

futuristically or what we're doing right now to prepare for the future.

So we're building on the important work of the NRC. So I'm going to show you two examples of a number of examples that relate to over reliance on technology. In this particular case, it's using cone beam CT, an over reliance on cone beam CT. So in the first case, it's a hypofractionated treatment for vertebral body. Unfortunately, the wrong vertebral body was treated for two out of five fractions because the cone being locked on to the wrong vertebral body. It was appreciated on the third fraction.

In another, as part of our data mining, we look for other examples of this and this is a situation where there was a large field size or there was a large shift of five centimeters and it was appreciated by the physicist who was doing the weekly check that the cone beam was too small for this type of field that was used and it wouldn't be accurate enough and suggested complementary approaches.

So we came out with a recommendation from these two examples and a number of other ones, the policies and procedures, when there are large shifts, how do we -- what can people learn from these examples, how to use cone bean CT maybe more appropriately, maybe

need to be larger when there are opportunities for making mistakes, especially when vertebral bodies can look alike, and having complementary types of imaging such as kilo voltage imaging or megavoltage imaging where it's appropriate.

I'm going to show you just again, everything that we're going to show you is the public domain regarding these quarterly reports. And the quarterly reports really reflect our evolution as we've learned and as we've gotten better and as we've reflected on what we've observed.

We initially talked about severe or almost severe medical events. We give case examples of time out procedures. We then talked about near misses, unsafe conditions, miscommunications, what happens when staff is rushed. And again, I've got to credit all the facilities for sharing all this information and not holding back on what they shared with the RO-ILS system.

As we got a little more evolved, we discussed issues about communication, electronic versus verbal because there were numerous instances we observed where we were seeing thematically the same thing again and again. I'll give you a couple of examples in a moment.

We got into near misses. In trying to categorize the near misses, we talk about -- there were some equipment issues. We got into a priority-scale issue because we appreciated the taxonomy had to evolve. For now, for near misses, we have a scale that goes from one to five in terms of severity just for near misses alone.

We talk about mistreatments and prescriptions, a number of issues that relate to HDR and IGRT, pacemaker policies and procedures, other things like that. And then finally, we came across equipment -- vendor/vendor issues and particularly with HDR and we shared this in our quarterly reports.

We have a categorization system about since it reached it patient there are near misses or we perceived as our unsafe conditions. And I mentioned for the near misses we've expanded that to a five point scale.

For a number of cases, what was planned and what was treated didn't exactly match and I'm just going to show you a couple of examples, but this is just from the data mining. These are repeat things that we find repeatedly that we're trying to disseminate to the community.

So the physician gave incorrect

instruction. The physician wrote 5 gray times 6 instead of 6 gray times 5. Sometimes in a hierarchical system this gets -- this doesn't get questioned, sometimes it does get questioned in trying to show that everyone makes mistakes and to empower and create a safe environment for reporting within a facility.

Sometimes the plan did not match the prescription and it was unappreciated at the time of approval and sometimes it's the last component of a safety chain. It's the therapist who is at the linear accelerator which picks up on this. Sometimes the planner wrote the prescription, so the written directive was not written by the physician. We've seen this in a number of cases and it creates all sorts of opportunities. For example, 12 and 2, so the dosimetrist receives a verbal order from the radiation oncologist to treat a shoulder 12 and 2. The dosimetrist wrote a written directive for 6 treatments of 2 gray each for a total of 12 gray. It was approved and it should have been 2 fractions of 6 gray for a total of 12 gray. It was picked up at chart rounds and then it was ultimately rectified. But it just highlights a number of things that we've observed as we've data mined the system.

Wrong hepatic lesion treated, especially

in the hypofractionated area with SBRT. We're seeing this more and more. So this isn't a teaching facility, and a physician resident reviewed the case. The resident ultimately contoured the wrong lesion. So the QA was completed and hemangioma was treated for five fractions. Only after the patient was followed up and showed progression in the liver, that they went back and looked at what had happened and they appreciated there was a geographical miss because they treated the wrong area and this eventually was treated. These are not isolated cases.

So the facility in this case appreciated there were a number of contributing factors. We've incorporated the facilities' observations and how they've changed practices and in our quarterly reports we emphasize a number of issues so this shouldn't happen at any facility.

So how do we further build on Subpart M? So as the RO-ILS system started taking hold and more and more facilities started reporting, we recognized that we needed to modify our forms. People are reporting -- the richness of the story is in the vignette. It's not in any particular field in the relational database. We also appreciated we were getting overwhelmed with data and we needed a better

way to try to evaluate things.

So we appreciated that there are different types of triggers that will allow one to bin data, data that reached the patient, data that was a near miss, data that represents an unsafe condition and then within these bins have different levels of significance so we can really spend our time more effectively in trying to figure out where can we connect the dots, how can we disseminate this, and what are the teaching parts from the database. So we've just implemented this and we're now starting to see -- we haven't yet seen the fruits of this labor.

The RO-ILS system is only two years old and I think it's a credit to the people at ASTRO and AAPM, as well as the volunteers, as well as the member institutions who through this labor of love, who are submitting information. At some places, it's the therapist, it's the physicians, it's the dosimetrists. At some places, it's mostly the physicists.

The way the system is designed at the initial level, anyone can submit-- it could be nursing. It doesn't really make a difference. Anyone should be able to submit to the RO-ILS system and then there's a second layer where you can provide the richness of the incident that happened.

At the Society meetings, we have various informational opportunities. We conduct educational webinars. We have tips of the month. We provide specific reports to each institution. We have safety alerts. We provide to the vendors reports in a de-identified way that explains what we found. Again, everything that we do is in the public domain and we certainly receive a lot of advice and suggestions from the community as to how we can make it better.

I'll just point out that Cindy Tomlinson, who's from ASTRO, who's in the audience can answer some specific questions regarding the RO-ILS system and with that, I thank you.

CHAIRMAN ALDERSON: Thank you. Thank you, Dr. Dicker. Because we have speakers on the phone who may be in their home institutions and have other scheduling issues, I'm going to ask us to hold the questions on the individual reports until we go through all of the presentations and then everything will be open and at that time we will ask the people on the phone if any of them are going to need to leave the session early or at some particular point and would direct the initial questions, if any, to them. So we'll carry on now with Dr. Elee.

MS. ELEE: Hi, I'm Jennifer Elee. I'm here

representing the CRCPD, Conference for Radiation Control Program Directors. It's been a while since I've talked to you in the past and I think there's some new faces. So is everybody familiar with who CRCPD is? Okay, if I needed to go into that.

I still chair the H38 Committee on Medical Events and I'm also the Healing Arts Council Chair now for the conference for two more years. I'm serving a three-year term as that.

So just a little background. In 2011, we did conduct a pilot and collected machining events for the first time. Since then, we've been collecting events from all states who have requirements. It's important to note that some states have no reporting requirements and some have therapy only, not diagnostic. And we only collect our events from the states themselves. We do not take them from facilities. So these are events that have been reported to a state and the state reports them into our system.

In 2013, we entered into an MOU with AAPM to further analyze the information that we get, the specific information on the event. We redact the facility and state information so they don't know where the events come from and they provide that back as an

annual report to CRCPD and the AAPM Boards and we both present a summary at the CRCPD annual meeting.

Why we collect information, we want to share lessons learned, prevent errors, look for trends and of course, improve patient care and safety. Our event definitions, we currently have event definitions for both therapy and diagnostic. We're very excited. Our definition of diagnostic was included in our latest version of the suggested state regulations for diagnostic x-ray. And as states adopt those, we hope to see more states have reporting of diagnostic events since that is the first time that's actually been included in the SSRs for diagnostics.

Our annual summary is a fiscal year summary, just so you know, 10/1 to 9/30. In total, for the period, we've had 187 therapy events reported and 9 diagnostic events. And that just kind of gives you an idea of over the years. It's been fairly consistent. We had a spike in 2014 on the number of events and states reporting, but overall our numbers are pretty consistent in the amount that we get.

Over the period, we have 20 states that have actually input events into the system, so we have 20 states that have actually put events in, some of them multiple years, but at least in one of those years.

The highest number of states responding in any one year was 37. Once we have our events in the system, we polled the rest of the states to see if -- just to verify either they did not have events or they do not have a reporting requirement. So we try to get a little more information on what's going on in the rest of the states. For those of you who do surveys, 37 out of 50 is a pretty good response. That's the best we've been able to do.

Types of events reported and in order to your font, these are pretty typical of what we see each year. It's pretty consistent, the types of events we see, wrong patient, wrong site, you know the weekly dose exceeds or the total dose or the single fraction. We do have a fair number of events that go into the other category and these are generally, we have a text field where they can explain what the issue is.

It is somewhat concerning that we still see wrong patient every year and two to three wrong patient cases every year which is astounding.

Severity of effects, we've only had two in the time frame that had severe effects that required some type of follow up. Minor effects are generally the response that we received or when we asked that question.

Events are discovered primarily by technologists which I don't think would be a surprise here and then physicists and physicians are primarily. We've had some dosimetrists and other people in the field.

Their chart check, quarter imagining clinical review, and again, we have 25 percent that indicate there was some other form of how their events were discovered.

Causes and contributing factors, therapist error. Again, this is a question where they can answer multiple things, so most of our events have multiple reasons. And usually it's therapist error and something else. There's a lot of -- several different boxes checked on those, but therapist error does come out a good bit.

On our diagnostic side, we've had nine events, four CT, three fluoroscopy, and one general radiography, four of the nine were wrong patients on the diagnostic side.

We had two which were exams done by unlicensed or untrained operators, exceedance to the lens of an eye, an unintended dose, and an equipment failure.

I think it's important that we note in

medical use of radiation we expose people on purpose for a potential benefit which is unlike a lot of the other radiation issues especially that NRC deals with on the industrial side. There's millions of procedures done every year. On our side, what we know we can do better is better disseminate our information outside of CRCPD and AAPM. We do a really good job of sharing it with each other. We go to our own meetings. We present it to our people. We put it in our newsletter, but I don't know how well we're doing getting that information to other people.

We continue to promote reporting of events to states by facilities and states to report to CRCPD so that we get more data. We try to follow up. Between now and the 15th, we'll make calls to all the states or emails to all the states who didn't report to the system to try to find out if there's anything they have.

I was asked to talk about safety culture a little bit and so I just picked a few points off the safety culture list and said for leadership knowing when and who to report to, I think is very important. And we're working on that. We realize that not everybody knows who they need to send their information to at the state level. So we're developing a list of

state reporting contacts. We're going to put it on our website. We'll share it with AAPM and ASTRO so that they can disseminate it to their members as well. It will include whether the state has diagnostic reporting, therapy reporting, and then who to contact at that state would be to send your events to so it's readily available for the people who need to report.

Problem identification and resolution and follow-up actions. This is something we're working with our inspectors on. Identifying a problem in the field is not as easy as it sounds when you're working with a facility that may or may not want to tell you that something has happened.

Personal accountability on the facilities part, owning up to mistakes, raising concerns, and respectful work environment, respect between us as the inspectors from the state and the facility has a long way to receiving more events and to finding out that these things are happening. I put this on it. I also applied this to the inspector or the regular. We need to be able to identify the problem. We need to be able to communicate with the facilities in a respectful manner.

We need to be able to continuously learn about new equipment and procedures. This is very

difficult a lot of times for our state inspectors and people in that area. We don't get the manufacturer training that the facilities get when units are installed. So a lot of times we're asking a lot of questions because we're just not familiar with a new piece of equipment or a new software system that you have or whatever.

We want to help facilities find resolutions and improve situations rather than just cite violations and encourage and give credit to facilities for reporting. I think that's a big thing. If facilities know it's okay to report, they'll have more that do.

What are we going to do in the future? We are looking at doing some topic training at our CRCPD meeting on safety culture and root cause analysis. So taking some events that actually happen at facilities and walking through them for our members so that we see what it looks like on your side. So what it looks like on your side, so we know when we go in what better to look for.

We're looking at never events. Our radiation therapy is looking into doing a handout on this, you know, basically, events that should never occur, wrong patient, for example. And this is a

problem. And we're also planning to do a journal article on our first five years of event reporting.

This is just the link to our reporting forms. They're on the website. And we email them in to our office.

This is my information if you need to contact me at any time.

I will say our interaction with AAPM has been very well received and very good. We have found at least one incident of a software issue that occurred in two different years in two different states which we were able to report to FDA, so that's our goal with this is to see things that we might not have seen otherwise if we were looking at them individually, but when we look at them all together, it's like oh yeah, that happened here and it happened there and they may not have even realized.

And as I said, we hope to see the diagnostic side pick-up with Part F and people adopting that. And our committee was initially set up to look at radiation medical events. We focused on the machine side because NRC was already -- had reporting on the materials side. And at the time that was where we felt we needed to put our efforts. But I think now we've got some water under the bridge and we're certainly open. We've talked

about it in the past to working with having a system where all medical events to be both material and machine into one system which would be nice for a facility. That's it.

CHAIRMAN ALDERSON: Thank you. So we're midway through these reports now. I would remind people that the reason for this session is that we're trying to learn how other organizations collect and report data related to medical events and we are considering the idea of how we move to an improvement culture, away from a punitive culture and excellent examples given just now by Dr. Elee from the CRCPD which is the Conference of Radiation Control Program Directorate. Thank you very much.

We'll move on now to the next speaker who is on the phone and he is Bruce Thomadsen, our former colleague and the immediate past chair of the ACMUI.

Dr. Thomadsen, are you ready to report?

DR. THOMADSEN: Yes, I am.

CHAIRMAN ALDERSON: Please, carry on.

DR. THOMADSEN: Thank you much. Thank you very much, Dr. Alderson. And it's really good to see all of you on the video and hear your voices. Missed you all, but you seem to be carrying on quite well.

Can I have the slides, please? And there is about a 20 second delay between the video, so I hope I don't get out of phase too much. I am the president of CARS. I'm also a professor at the University of Wisconsin.

Next slide, please.

And just information about the Center for the Assessment of Radiological Sciences or CARS. We are a 501(c)(3) non-profit Patient Safety Organization listed with the Agency for Healthcare Research and Quality and we're the same software that's used in the reporting system in the VA system, although because of regulations, their data and our data cannot mix.

Next slide, please.

The charge that all the PSOs have from AHRQ is to improve clients' quality and safety. And we take that to heart by working with our clients to remediate causes of any reported incidents. And we work with the clients to develop prospective quality management for their facilities also.

Next slide, please.

In our reporting system, the organization is that a facility that has an incident goes online and fills out a very short notice that they've had something happen with few details. And most of the details we

ask them for are only to get them -- to give them a feeling that they're actually involved in this reporting system. Because as soon as they submit the report, we get a notice that a new report is online and one of our staff calls the facility and talks with our contact there.

And we'll go through all of the questions in the questionnaire which we follow the AAPM-generated taxonomy. And we go through it to make sure that we understand exactly what's happened in the incident and that the data being entered on the form is correct.

We also then after we get all the information on the form, we'll go off and we'll do a causal analysis of the event. We'll then put the form back on line with all of our analysis and our proposed solutions for what to do to improve the quality at the facility.

We'll then talk with the contact at the facility, go over our analysis to make sure that we have understood what's happened and they agree. And go over our proposed solutions because we understand that we might make proposals that would be infeasible at the given facility and so we'll work back and forth with the facility until we can come up with what would be a useful set of recommendations.

And we do the analysis because from a study we did back in the '90s of causal analysis of radiotherapy events, we found that there's a very long learning curve and that persons who do not have a lot of experience doing causal analysis usually come up with very superficial ideas of what the causes were and generate very simplistic proposed correctives that would have prevented the given event, but don't really delve deeply into the system at the facility that actually led to the weakness that manifested itself in the event.

Next slide, please.

The data, as soon as the initial report is submitted, goes into our database. And let's see, I'm on -- okay. All the fields -- I think I'm on -- I'm seeing -- no, this is the right slide. The delay sort of makes it a little difficult to check where I am. But all the incidents do go into the database which is important to trigger the protection that the facilities would have against the legal discovery. All fields are completed in our reports and we make sure that they're all correct.

The root cause analysis is done by professionals who have expertise in both radiotherapy and in systems analysis and we make a point of trying

to support our clients as they're trying to improve their system. We work with them directly.

Next slide, please.

The system does serve as the local database for our clients, but it also is automatically part of a national database when any researcher can register and view and anonymous data from the system. We also accept anonymous reports. If the anonymous report identifies that the incidents happening at one of our clients, we can then go back and work with our client to try to improve the situation.

Next slide, please.

We do send out information through emails to clients, messages to list servers, and letters to professional organizations.

Next slide, please.

Just some of the findings that we found are that it's very important not to get too hung up with evaluating the severity of incidents that are reported. When we're trying to help a facility prevent having a major event, and analyzing each of the small incidents. Even those that had no effect, no severity on the patient are very important because they do identify weaknesses in the system. And by following incidents that happen at a given institution over time, we have

been able to identify definite problems in facilities.

Just two examples are listed here. One facility had a number of number of incidents reported and what we were able to identify is that the problem behind it -- well, each one, if you looked at them individually, had causes that looked apparent. Underneath those were a problem with the scheduling, where the scheduling would end up with many patients being started at the same time and then many lulls by the time of lulls between patients. And they were staffed for the average between these two and they weren't really prepared for the higher patient load. And this was periodic almost in the swells about a monthly or bimonthly basis. Their events were occurring during the busy periods and almost all of the events tended to be omissions. That is, they got busy and just missed some step that they were doing.

Another problem that we identified across events occurring at a given facility was that they had no systematic approach to communication and while each event again had causes that something happened that looked like it was a simple case, underlying everything we could see was a constant communication failure that they just didn't have a systematic way of dealing with communications.

Next slide, please.

Another one of the problems that we noted that we were dealing with was a problem where there was an omission of a device in a treatment set up. The slide is showing the order form that had been used. The top red arrow is pointing to a box where they would enter comments about this set up. The lower arrow is a checklist where they check off things like the immobilization devices.

In this particular case, there was a long comment on how to set up the patient and the therapist and the simulator followed the comments, but as they were following the comments, they thought that that was pretty much describing all of the set up and they didn't notice the immobilization device checked off at the bottom.

Next slide, please.

And one recommendation we gave was to reorder the information on the order form, moving the check boxes up above the comments because when the comments is filled out, the therapist is unlikely to notice -- to miss the comment that's written in there. And this brings the eyes down following human factors analysis, brings the eyes down through the checklist that is giving them the first indication of how the

patient be set up and then leading them to the comments. And this type of a change should help improve the communication on how to set up the patient.

Next slide, please.

CARS also has a section for reporting equipment failures and we accept reports both from our clients and from just anybody if they have an equipment failure. If there is an incident from a client that's reported, we will automatically go in and enter the equipment failure.

We then will go to the vendor and discuss the problem with the vendor and come up with what their solution would be and we try to assess whether that would fix the problem and we would disseminate this information not just to the people reporting it, but on our website and if it's relevant through an information release. If it's appropriate, we also will take these reports and with the client's permission, we will enter them on the FDA website.

We feel it's very important to actually work with the patient -- with the client, rather, on dealing with their problems because we have the expertise in causal analysis and probably very few of the facilities have had enough events where they've gotten past the learning curve and can reliably

identify what the true causes of the problems are.

We also have found it's very valuable to work with the clients across their incidents to gather more information about what may be underlying the problems. So we were the first PSO taking events from the radiotherapy community.

We have found that the approach we have does help give better data and thorough data in the report and we can support our clients and get more information about them by getting to know them and following them across incidents.

Thank you.

CHAIRMAN ALDERSON: Thank you, Dr. Thomadsen.

We'll move on now to Sandy Gabriel from the International Atomic Energy Agency who will tell us about the radiation oncology safety system known by the acronym SAFRON. Ms. Gabriel?

DR. GABRIEL: Yes, thank you. It's good to be back with my old colleagues again. And I'll wait for my title slide to show up. Again, we have a 20-second delay that may interrupt the presentation a bit.

So thank you for inviting the IAEA to provide an update on our radiotherapy incident learning

system called SAFRON. Debbie Gilley is the SAFRON project manager and she's traveling on IAEA business today, so she asked me to make her presentation for her.

Could you please move ahead two slides, Sophie?

So in the name SAFRON, SAF stands for safety and RON stands for radiation oncology. SAFRON is an international incident learning system developed by the IAEA to improve and promote safe planning and delivery of radiotherapy. Its purpose is to share information, promote safety and clinical facilities around the world, and provide resources for prevention of future incidents. Thank you.

SAFRON includes data from a variety of sources. It contains reports submitted directly by individual radiotherapy facilities as well as data shared by other reporting systems and organizations. These include ROSIS, the Radiation Oncology Safety Information System, which is based in Europe; ASN, the French regulator of nuclear safety radiation protection; and CRCPD, who we've heard from a few minutes ago.

SAFRON is a web based voluntary reporting system of incidents and near misses. It became operational in December 2012 and is initially limited

to external beam radiotherapy. As of mid-September of this year, SAFRON contains 1334 reports. There are currently 75 registered contributing institutions from 6 continents. Reporting to SAFRON is anonymous and therefore non-punitive.

Next slide, please.

So SAFRON was designed to perform several functions. It serves as both a local and international incident learning system. For individual participating facilities, SAFRON can be used as a local database of incidents and near misses with analytical tools such as statistical data and charts. By anonymously sharing events, including detailed narrative descriptions, SAFRON participants can enhance the knowledge of staff and other facilities.

On an international level, SAFRON offers a resource for the radiation oncology community to improve quality and safety. In addition to the analytical tools in SAFRON, IAEA staff provide information in the form of reports and peer-reviewed publications.

Direct access to the contents of the SAFRON database is available over the Internet to anyone worldwide who completes a simple registration process in the centralized IAEA access point called NUCLEUS.

An additional level of registration is required to become a participating facility that can enter data into SAFRON.

Next slide, please.

The next few slides will show examples of different pages in the SAFRON website. We'll wait just a minute until the first one shows up.

So the first image that I hope will display -- there it is, is the current version of the first page that is displayed after you login to SAFRON. It has links to various functions within the system as well as summaries of featured recent incident reports and recent related publications.

There isn't enough time today to demonstrate all of SAFRON's functions so I'll focus on a few that were not covered in Debbie's presentation to this committee in 2014.

Next slide, please

SAFRON provides a variety of search parameters and report types. Participating facilities can choose to view either their local data or data from the full database. Everyone else is limited to viewing anonymized data from the full database. Let's wait for next image.

This slide provides an example of the

screen that is displayed if you wish to search for incident reports. You can search on a variety of different parameters or on the text of the narrative description. The search field demonstrated on this slide is clinical incident severity. So the search is done using a pull-down menu in that circled area on the left of the slide to select one of the seven categories of incident severity.

You got a little bit ahead of me, Sophie. Okay, we'll switch to this one.

This slide is an example of one of the statistical reports in SAFRON. It shows incidents that reach the patient in blue, versus near misses in red by year. You can see that right now there's a relatively small number near miss reports that have been submitted or captured, although the IAEA does recognize the importance of near miss reports and encourages participants to submit them. IAEA staff have noted that the majority of reports are events that reach the patient, but may not meet criteria for making the reports a regulatory body.

You went back to the previous one. Let's move ahead to, please, to the slide that has lots of colors. Next one after this.

So one parameter included in SAFRON

incident submissions is the way in which the incident was discovered. SAFRON device is delivery of external beam radiotherapy into 92 process steps divided into three phases: nonclinical, pre-treatment, and treatment.

This slide shows the results of the summary report illustrating the ways in which incidents in each phase were discovered. You can see from the green bar in the center portion of the graph that the most frequent discovery of incidents was by chart check before the initiation of treatment.

Next slide, please.

This slide shows the total number of incidents reported for each phase of the radiotherapy process. To see a breakdown of the number of incidents for each process step within a phase, you can click on that bar in the graph to produce the more detailed report shown on the next slide which I hope we can get to fairly quickly.

Okay, the slide with quite a few bars displayed that I'm not seeing quite yet shows the result -- if you click on the bar for treatment phase in the previous slide, the graph shows the number of reports associated with each process step in the treatment phase. Note that there are more than 30 process steps

in this phase, so you would need to scroll to the right to see the full graph. If the user identifies the process step that they would like to improve or research, SAFRON provides links to related professional publications and other educational resources.

Next slide, please.

Another important concept used in the SAFRON database is safety barriers which are steps in the process intended to catch errors. Incident reports include three fields related to safety barriers: what safety barriers fail to identify the incident; what safety barrier identified the incident; and what safety barrier might have identified the incident if it was in place.

This slide shows a summary report of the safety barriers that failed in each phase of the radiotherapy process. You can see that some of the reviews and checks intended to service safety barriers were not always effective. For example, in the treatment phase, the bright pink bar represents 25 reports of incidents in which image based position verification failed to identify an incident. Several of these involved online image match to the incorrect vertebral level, similar to incident Dr. Dicker

discussed today in his presentation.

Next. Let's skip the next slide and move on to the one that is titled SAFRON Learning which I presume you can already see, although I can't quite yet.

The final group of slides discusses the way in which the IAEA has been using SAFRON as a learning tool to improve safety and quality in radiotherapy. Our staff has made numerous presentations to international regulatory authorities and medical groups on incident learning in radiotherapy of the benefits of using SAFRON. The IAEA produces SAFRON newsletters, usually twice a year, addressing issues or trends that have identified reports of incidents entered into the database. Topics addressed in the three most recent newsletters are safety culture and radiotherapy, learning from near misses, and a quality process called check review and report that can be used to resolve errors before they reach the patient.

Next slide, please.

Based on analysis of events in SAFRON, the IAEA recently published a brochure on the check review and report process. This brochure reviews the kinds of checks that can be used to safety barriers, strategies to perform effective checks, the importance of resolving any identified discrepancies, and

benefits of reporting incidents and near misses.

Next slide, please.

Another learning opportunity stemming from SAFRON is a new IAEA e-learning course on safety and quality in radiotherapy that will be available online by the end of this year. This free course 12 modules covering topics such as failure mode effects analysis, root cause analysis, incident learning and safety culture. Three radiotherapy errors are used as case studies to illustrate these topics.

Would you move ahead two, please, to the slide called SAFRON Next Steps?

The IAEA plans a series of updates to expand SAFRON's capabilities. Within the next year, we intend to add a perspective risk analysis feature and the ability to address brachytherapy events using process steps designed specifically for this modality. I hope you can see the slide called SAFRON Next Steps. There we go.

In the future, we also plan to add translation capabilities so SAFRON can be used by speakers of languages other than English and the ability to address nuclear medicine events.

Next slide, please.

As a final point, we like to be sure you

are aware of the series of international conferences on radiation protection in medicine that relate to the topic of today's discussion. In 2012, the IAEA and the World Health Organization co-sponsored a conference in Bonn, Germany to identify and address issues related to radiation protection in medicine. This was attended by 536 individuals from 77 countries and 16 organizations. The conference prioritized ten actions to approve radiation protection in medicine during the next decade and published these as the Bonn Call for Action.

Action 7 says improve prevention of medical radiation incidents and accidents. There are five sub-actions, the first of which is implement and support voluntary educational safety reporting systems for the purpose of learning from the experience of safety-related events in medical uses of radiation. A follow-up conference will be held in December 2017 at IAEA headquarters in Vienna to assess progress on implementing these ten actions. We hope you will all consider participating.

And I think I am going to stop here on the last slide. You can see contact information at our website, rpop.iaea.org. And if you would like to learn more about the IAEA's activities in the radiation

protection of patients, you can also send a message to Debbie or me at the email addresses shown on the last slide.

So I'll end here and try to answer any questions. Thank you.

CHAIRMAN ALDERSON: Thank you very much. So we're now going to open up these four discussions. Two comments, we've heard from four respected organizations that collect data from a broad participant basis in non-punitive ways in an attempt to improve patient safety. And we listened to them so that they may inform how the NRC might wish to consider some of these similar approaches.

We'll begin with comments from the ACMUI members and then move to our in-house audience and then to listeners on the phone who might wish to comment and we have approximately 20 minutes for this Q & A session.

So the floor is open to the ACMUI. Dr. Zanzonico.

VICE CHAIR ZANZONICO: Well, thank you all. I mean very, very informative. One thing that strikes me when I'm listening to these reports from diverse groups, diverse organizations is, is there any effort, any value in collating reports from multiple groups?

I'm wondering is there redundancy of reports among the groups or does each group have its own constituency? So when you hear these presentations collectively, it makes it kind of difficult for one listening to it, at least for me, to get a sense of what is the prevalence of these different kinds of events in the field without some collective collation of the data.

So whoever would like to sort of comment or address that point?

CHAIRMAN ALDERSON: Dr. Dicker.

DR. DICKER: So, three points. One, I'm going to use a lifeline to Ms. Tomlinson. Two, we have about ten percent penetrance in the radiation oncology community in the past two years. I don't know if it's going to be linear, logarithmic, geometric in terms of our penetrance. And Ms. Tomlinson will talk about working with other societies.

And then the other comment I think you relate to is if we have a de-identified relational database, is there a way to merge databases, right? That's kind of a technical thing.

So Ms. Tomlinson from ASTRO.

MS. TOMLINSON: Cindy Tomlinson from ASTRO. So part of the problem with merging things is

that under the Patient Safety Act and the way that RO-ILS and CARS also operate, is that there's legal issues. And so the Patient Safety Act gives legal protections to the data. And so when you start bringing in other things and moving that data out, you have to be super careful with how you are making sure that it's anonymous and de-identified and all these other things

So it's not as simple as just merging the data. I mean we're all looking sort of at the same data points, but trying to merge them, brings in some technical, but mostly some of the old issues as well.

Is it not on? Can you not hear me? Do you want me to repeat that?

CHAIRMAN ALDERSON: Could people who were on the phone, could they hear these last comments?

DR. THOMADSEN: No.

CHAIRMAN ALDERSON: No. So please repeat the comments.

MS. TOMLINSON: I'm really sorry. It's Cindy Tomlinson with ASTRO. Hopefully, I can repeat it the same way that I did before. But basically, trying to merge a lot of these databases especially with RO-ILS and CARS who operate under the Patient Safety Act is difficult.

There are protections that the Patient Safety Act gives to that data, and so taking that data out requires a lot of work and there's some technical issues as well, but mostly it's the legal issues with merging all of that stuff together.

The CRCPD database, again, it's the states that require reporting who then send that stuff off to CRCPD. That stuff is in the public domain anyway, but our data, especially since we're looking at near misses and sort of other things that are -- I want to say not major because that's not the right word, but that don't rise to the level of state or even federal reporting, it would be really difficult, I think to do that and maintain the protections. Because that's the reason why people participate in RO-ILS, one of them, is that there is protection of their data.

CHAIRMAN ALDERSON: Do we have further comments?

MS. ELEE: I was just going to say with CRCPD, Cindy is right. We collect information from the states that is reported to the states. Any of those events are available through a FOIA request to that specific state. CRCPD does not release any states' information. We collect the data. We aggregate it, we look at it. We do provide our information to IAEA

and it is put into the SAFRON system. We are registered users, CRCPD is, so they're put in as, I guess, CRCPD events, not individual states events, but they are included in that system.

CHAIRMAN ALDERSON: Dr. Thomadsen or Ms. Gilley, do you have comments on this question?

DR. THOMADSEN: Yes. I would just say that CARS and RO-ILS data do not overlap that I know of. I don't think that we have any clients who are in both systems. We have talked with the RO-ILS advisory and analysis group about trying to combine data. AHRQ does try to combine data from all of its PSOs. Unfortunately, its database that we could upload into is not made for any of the information that's really relevant in radiation oncology. So we would be trying to work between the RO-ILS system and the CARS system to try to combine data and make sure that there is not overlap. The taxonomies are pretty much the same, so that is not a barrier.

As far as events, we've actually not had an event in our database which would rise to the level to go into the CRCPD's or the NRC's, but we do have a data field that tells if the event is reportable in which case it would be identified as an event which could be in either of those databases.

We are going to be talking, actually just next month, with Debbie Gilley to see what, if any, combination of data we could have with SAFRON.

CHAIRMAN ALDERSON: Ms. Gabriel, any further comments on this?

DR. GABRIEL: I think the focus of SAFRON is a bit different in that we're worldwide and the IAEA does quite a bit of work with developing countries who are starting new radiation oncology services or trying to expand the ones that they have. So our focus is somewhat different.

As we've already discussed, we do cooperate with other systems and organizations in trying to service a clearinghouse to collect lots of different reports.

CHAIRMAN ALDERSON: Thank you. The next ACMUI question comes from Mr. Richard Green.

MR. GREEN: There's a great deal of value in getting an aggregation of the data so we can see the whole picture, but with anonymized data, it just seems you've got your clients and they've got their clients and how do we know we're not double counting? That's the challenge I see.

CHAIRMAN ALDERSON: Other comments?

DR. THOMADSEN: This is Bruce Thomadsen

again. At the moment, between the RO-ILS and CARS you wouldn't be double counting the data because the clients are separate. Although it's totally possible that somebody who is a client of RO-ILS could be a client of CARS, too, because we do offer different services. That would be one reason why it would be very good for RO-ILS and CARS to be able to cooperate in trying to combine data in some way that would prevent that.

CHAIRMAN ALDERSON: The next ACMUI comment is from Dr. Dilsizian.

MEMBER DILSIZIAN: Thank you very much, Dr. Alderson.

I want to congratulate to all the presenters. It's a wonderful start and I think that the reason we're having this discussion is because we really feel that the number of programs or number of incidents is just the tip of the iceberg. And I think that the SAFRON presentation of the clearinghouse of multiple reporting systems of 4 organizations and individual clinics that represent only 75 programs in 6 continents tells us that we can't do anything about prevalence of anything here because we're talking about very small number of those who are reporting.

I guess the challenge that our committee is going to be dealing with is how do we expand that.

CHAIRMAN ALDERSON: Dr. Langhorst?

MEMBER LANGHORST: Yes, I wanted to bring it back to what -- not necessarily that we gather all this data and learn -- I want to know what you think ACMUI and NRC can learn from your experiences to help us in advising the NRC as medical event reporting.

One of the things that I wanted to ask Ms. Elee was the fullness of information that your states gather from their facilities. And you speak about giving credit to the facilities and I wanted to learn a little bit more about what that meant.

MS. ELEE: Well, I think and I think just to address another question or maybe make a point is that we're a little different in that we are -- we don't collect from facilities and that was discussed at the beginning. And the reason is we don't want to make double work on the facilities. So if they're already submitting it to the state, we don't want them to have to submit it to us, plus there's the issue of if one group gets the certain amount of information and another group gets different information, that kind of thing.

The other thing that we discussed early on was near misses. We don't collect that because we are representing regulators. And if you have a near miss,

and you caught it, your system worked. We like that. So we didn't want to put those in our database because they really aren't relevant for us. They're very relevant for the facilities to learn from, but on the state side it would clog the system with things that could happen.

MEMBER LANGHORST: Also I wanted to add the inspectors being able to identify it.

MS. ELEE: Right, and that's where we think we need to do better. We think we need to help our inspectors learn how to look for events. Or maybe what the right questions, open-ended questions are to ask facilities. For example, and it's more on the diagnostic side than the nuclear side, but maybe relevant. It's not do you have events, but do you ever x-ray the wrong patient? What happens when you x-ray the wrong patient? How do you deal with that? And I think those are questions we need to learn to ask better and maybe there's a better way to do that. A lot of facilities handle those a lot of different ways and we need to figure -- they may, I dare say, some write orders for patients that they x-ray incorrectly, therefore, it's not a reportable event, because now there's an order. So there's things like that that we need to figure out how to talk to facilities about. And that's

something Lynne and I have discussed of having training at our annual meeting for inspectors.

CHAIRMAN ALDERSON: Thank you. Before we go on, there's some other hands up in the room. I'd like to ask people, not our invited panelists, but others who might be on the phone listening to this discussion, are there any questions out there from the public? Would anyone like to speak who is on the phone?

MEMBER COSTELLO: This is Frank.

CHAIRMAN ALDERSON: Yes, Frank, please. Frank Costello, one of our members in absentia today. Frank, please speak up.

MEMBER COSTELLO: Thank you, and sorry I can't be there today, but I'll try my best to be there in the spring.

A question for any of the panelists. Many of you mentioned that these are data made anonymous and the NRC system, when a report comes in and it goes to the WHO, it's put on the website. It's not made anonymous.

How important -- what advice do you have for the NRC as far as making these reports anonymous or keeping it as it is where it's identified with a particular licensee?

CHAIRMAN ALDERSON: That goes to any of

our invited panelists.

DR. DICKER: Yes, I'll just say --

CHAIRMAN ALDERSON: Please identify.

DR. DICKER: I'm sorry, Adam Dicker, representing RO-ILS.

Our system is designed to scale and we've seen a flood of reports as institutions have come on board. And it's the protection that AHRQ through a patient safety organization in the de-identified way. In fact, none of us who participate on the advisory capacity of RO-ILS can be a surveyor for the AAPM/ASTRO/APEX accreditation. So we take this pretty seriously and we see incredible volunteerism, especially for things that did not for near misses and other things, for unsafe environments, stuff that you would never pick up at the level of the NRC. So we think the de-identified is incredibly important.

DR. THOMADSEN: This is Bruce Thomadsen for CARS. Likewise, I think if the information is going out to the public, if it were not de-identified, the likelihood of reporting would drop to zero for the most part, I would say.

So the anonymous reporting and the anonymous data that goes out to the public is essential for trying to get the information to the community so

that they can learn as well as those of us who are actually working for the PSO and have to work with the facility, so we have to know who it is. But for the public, it would have to be anonymous for that data to even be here in the first place.

MS. ELEE: And I would just point that although CRCPD does not give out any state or facility information, the state that the event was reported to does have that information, very similar to NRC, so it's not really anonymous.

CHAIRMAN ALDERSON: Comments from the audience here in-house at the NRC? No, but Dr. Ennis has a question.

MEMBER ENNIS: This will be for any of the presenters. The protection and anonymity seem to be key, but I'd like you to put on the NRC hat for a moment and view it from the perspective of a requirement to protect the public from excessive exposures. And do you think that the current system and its lack of anonymity, if you will, actually interferes with the ability to protect the public or are these just complementary ways to get different layers of information so the highest level it's appropriate, but lower levels, near misses, the protected environment works? Are these complementary styles or are these

really conflicting styles that we need to grapple with throughout the entire event process?

DR. THOMADSEN: Can I take that one? This is Bruce Thomadsen again.

CHAIRMAN ALDERSON: Yes.

DR. THOMADSEN: I think that we could take a lesson from the aviation industry which started making not only reports of problems -- it wasn't a matter of anonymity, although it was, but lack of punitive efforts in enforcing problems that happened, even if there was a violation that may have occurred, not by something like being drunk while flying or sabotage, but by an accident.

People who have those problems could report and in the reporting are protected from punishment. We could learn from that -- and what happened was, you don't then have the ability to punish the people who committed an error, but in the long run, they found that their reliability and safety and quality improved remarkably with this system.

And part of the problem with a database that's based on a regulatory framework where the names are public and it's based on potential punishment is that the information that's given to the inspectors may be reserved. They may not -- the inspectors may not

get all of the information that the facility might think relevant to the event just because they would be afraid of that information being used against them. And so all that information which might be very relevant to an event and could be helpful in preventing events that were similar in the future becomes lost.

CHAIRMAN ALDERSON: Yes, Dr. Dicker.

DR. DICKER: I'd like to connect to make an arc to something you talked about a little earlier before this session. How can the NRC help? Well, if you look at training programs for therapy, for dosimetry, medical physics, radiation oncology, and then you look at the certification process, what is the -- how much emphasis is on patient reporting? Do people know at the dosimetry or therapy level about patient safety organizations?

So it's not so much that RO-ILS is the best or CARS or something, but they should belong to something, right? And what is that awareness within different communities that are involved in the chain of safety that touch a patient?

So I think the NRC can make in its own regulatory manner whether it's suggestions or encourage or having it as a badge of honor that you participate in some type of PSO like -- or incident

reporting event. So I think that's where the organization at the training level can have influence, if not making it a reg.

CHAIRMAN ALDERSON: All right, other questions or comments from within the room? There's one here in the room. Please identify yourself.

MS. FAIROBENT: Thank you, Dr. Alderson. Lynne Fairobent with AAPM. I just want to make a couple of points. I agree with what Dr. Thomadsen just expressed, but I think it's important that we remember that what is reported to NRC to get to the issue of identification or not are regulatory, reportable events. They're not as with the CRCPD database, they're not necessarily collecting near misses. Although something that may be reported, the licensee is unsure if it's reported or not, errs on the conservative end and will report something that may turn out then not to be reportable event.

My biggest concern and problem is that the NRC database is not publicly available for us to do trending analysis on what is officially reported into NRC. So although we can do, collectively we can do trending analysis on what is in RO-ILS, what is in SAFRON, we do trending analysis with CRCPD and what's reported in their database. CARS is doing trending

analysis.

We do not have access as the public, to do trending analysis on the NRC's nuclear medical event reporting system. And that to me is problematic because yes, we learn from what we may see on near misses, but I don't know that we have had a system of where you can step back and take a look at are there trends on actual reportable events that we should be picking up earlier? Are there trends on perhaps differences in inspection and compliance analysis? And this may be, I don't know, may be able to be determined if we can access the database to see what is actually being reported in.

Yes, we can piecemeal all this together because the initial reports come in to the emergency ops center and you could then track them and track them through ADAMS, but it is a cumbersome way to go about that.

MS. ELEE: To your point, we might could, and I'm making some notes, at least CRCPD could and maybe it would be interesting to know how many of the events that are put in actually result in a punitive fine. I mean I think probably most of them at the state level are going to result in some violation letter or that kind of thing, but how many of those are actually

punitive I would guess a small portion which we could survey and find that out for you.

CHAIRMAN ALDERSON: Thank you. We only have a few more minutes. I'm actually going to let the session run about three minutes longer because the previous open session ran over time, but we will be closing this session down in just a few minutes.

Sophie, do you have a comment?

MS. HOLIDAY: Yes, I know that you asked for people on the phone if they had comments.

CHAIRMAN ALDERSON: I did.

MS. HOLIDAY: So at this time I would like to ask the operator if you can check to see if there are any members on the phone that would like to make a comment or ask a question.

CHAIRMAN ALDERSON: Thank you. Did the operator hear that?

OPERATOR: The line is open for questions. If you'd like to ask a question, please press *1 and record your name. Thank you.

CHAIRMAN ALDERSON: Hearing none, I will assume that there are no people out there who wish to comment who have not commented up until now. We'll take a last comment here.

Dr. Langhorst, do you wish? And then

we'll go to Dr. Collins.

MEMBER LANGHORST: Okay, I just wanted to say thank you to all the panelists. One thing I wanted to ask Ms. Elee is when you start going into the NRC required reporting data, will your states have to put that in NMED and then your database?

MS. ELEE: That's why we haven't done it.

MEMBER LANGHORST: Okay, thank you. Thank you.

CHAIRMAN ALDERSON: Dr. Collins.

MR. COLLINS: Thank you, Dr. Alderson. I just wanted to for context share with everybody here that the NRC's enforcement policy or process does consider actions by the licensees. So when there is a violation, when we're reviewing it, and making determinations about what, if any, enforcement is taken, we do look at whether or not the issue was self-identified by the licensee and what corrective actions are taken by the licensee and whether or not they're prompt and comprehensive. So it's not like we're flying in the blind on that. So I just wanted to make sure that that context is out there.

CHAIRMAN ALDERSON: And I'll just take the chair's prerogative to make two closing statements and then we'll bring this session to an end.

Things that I heard that might not be controversial and that might be able to be achieved would be if issues came up through the NRC system with a licensee to check whether that licensee is, in fact, in some sort of quality improvement organization and if they aren't, well then that perhaps should be part of the advice that that particular site receives.

And regarding the comment about the lack of accessibility of the NRC database, I would suggest that that's not easily resolved, but in fact, one of our current initiatives here in the ACMUI is to improve communication with our outside partner organizations. So in fact, if we could internally decide what triggers communication, if there is a trend, and then make that trending available to some of these outside QI organizations that might fulfill some of that need.

But I would like again thank everyone and Dr. Langhorst for organizing this excellent session and that will bring us to a close. We're now on break until 10:30.

(Whereupon, the above-entitled matter went off the record at 10:17 a.m. and resumed at 10:33 a.m.)

CHAIRMAN ALDERSON: We'd like to reconvene now for the next portion of the meeting. This is the

Medical Event Subcommittee Report. Dr. Ron Ennis is ready to give us that report.

So, Dr. Ennis, you are on.

DR. ENNIS: Thank you, Dr. Alderson, and good morning everyone.

This will be the annual report of medical events for Fiscal Year 2015. I want to start by thanking my Subcommittee members, Dr. Langhorst, Dr. O'Hara, Dr. Palestro, Dr. Suh, and Dr. Zanzonico, who helped in various ways in putting this together, and if there's discussion, may even speak to some of the events as needed.

And, I also want to thank Dr. Donna-Beth Howe for her comments on our report as it was being developed.

So, we will start with 35.200, unsealed byproducts for imaging and localization. So, in the current fiscal year, there were four such events. Three of them involved technetium, two from myocardial perfusion studies, and one for lymphoscintigraphy, and one thyroid I-123 event.

In a little more detail, the technetium events, one of them was technetium pertechnetate, instead of technetium-sestamibi was used. Another one, again a different technetium product was confused,

the one for the other, failed to follow proper procedures in detail were felt to be the causes of those.

The lymphoscintigraphy events, I think again, not again, was a technologist not identifying the proper patient, and dosage.

And, the other event was the wrong activity delivered by ten-fold, and was attributed to "human error." Someone, presumably, put a decimal point in the wrong place, or misread the decimal point.

Moving on to unsealed materials that require written directive, there were seven events. Five of them involved I-131. One involved radium, and one involved this monoclonal antibody.

And similar themes again, the first event was a overdose, almost 45 percent, again, technologists failing to confirm the activity.

Second event, ten-fold, so a decimal point issue it would seem in that the written directive was written incorrectly.

The third one involved a significant overdose as well, with the technologist selecting the wrong vial and not confirming with the written directive.

And, the last one involves double -- half

a dose, excuse me, technologist was supposed to have delivered two capsules but only gave one.

And, the last of this group was not really very well described, so it's hard to know exactly what happened. This was a 21 percent under dose, and it is described as "failure to follow procedures."

So, certainly, these are all fairly similar in their issues, I would say.

The radium events, again, a similar thing. The dose was almost double, and it was attributed misreading a prescription and administration of the incorrect dose because of that.

And, iodine monoclonal antibody, this was a different issue, which we will see later on. In other settings, this also occurs, as you'll see later on, but here a leakage of a catheter connector that they hadn't noticed on visual inspection.

So, that's the events of unsealed sources for the year that have been reported.

And then, for 35.400 events, so HDR events, so these are the trends over the last few years, then comments from the last session about trending analysis. So the number events is small, so trending analysis was, obviously, kind of limited. And, I would say that there's no clear trend here. The relatively small

numbers is the only consistent trend.

In terms of the specifics of the events of this year, so this is something we haven't seen to my recollection recently, but head and neck implants with iridium wires, these are placed and left in the patient while the patient remains in the hospital for a period of hours to a day or two.

And, in this event the patient was checked in the morning by the MD; everything looked good. And the MD did rounds on the patient midday. One of the sources of the iridium wires was missing.

They searched, whatever, and they found it in the linens that had been changed around 10:00 a.m. So, the presumption is that it fell out or was pulled out in some manner between the morning check and the bed linen check, maybe involving the bed linen check around 10:00 a.m.

So, it was found at noon, and it was reinserted; the treatment was completed from a dose delivery point of view. The facility and the regulators agreed later that there was no event there, but the regulators on the site visits thought there may have been an unintended skin dose. If that source had been lying in the bed linens along the patient's side, for example, for those several hours, it could have

yielded a dose that would qualify as a medical event through the skin.

So, it was then reported to the NMED there. According to the licensee there was, actually, no patient toxicity related to this and that they dealt with this by writing a new policy, presumably, about how bed linen is changed or something along those lines. It was a little vague in the specifics.

Another -- there were seven events in prostate brachytherapy. In one, the physician mistook the penile bulb for the prostate. So, this is something we saw last year, from our recollection as well, a couple of times. It doesn't seem to happen commonly. There's one or two a year, but the prostate bulb is a structure that's at the base of the penis below the prostate. It is round, and can confuse someone to think it's the prostate if they're too quick to make that assumption.

The licensee, actually, attributed it to calibration changes on their ultrasound unit that had been done just prior to that procedure. That is my own editorial comment that I'm surprised there was no attribution to the MD in this error, but I wasn't there to say for sure.

So, they implemented a procedure to be sure

their ultrasound is double-checked prior to using it after any service, which does seem to be a good policy to have in place.

Other events related to prostate brachytherapy, some of these are going to reflect things that in the new rulemaking may not be events, and maybe are examples of why the rulemaking is needed, but they are reported as of now, so we'll review them.

In one case, this does not fall into that comment that I just made I would say, the source ordered based on air kerma rather than millicuries, so there was some confusion there between what was prescribed and what was ordered. So, they ended up delivering 20 percent more dose because of that error, and they just implemented new procedures and labeling to make sure everyone is talking the same language throughout their process.

In another case, which again does not fall into the category of things that would not -- this would still be an event. It's my understanding it should be. The dose delivered was more than intended in a significant way. The error, essentially, is that prostate brachytherapy can be done in combination with external beam, and then it's called a boost, if you will, and the dose is discounted to a degree because

of the external beam that's delivered, or it can be done as sole treatment.

And, essentially, this patient was supposed to receive boost implant to be combined with external beam, but instead they did a full dose implant, which was not their intention. And, the decision between those two is a medical one, but once they made the decision to do one, they didn't follow through on the one that they did. They dealt with that medically by just not doing the external beam part of the treatment to not further overdose the patient, but clearly that wasn't really their medical intent to begin with, so it was an event.

And, they corrected -- tried to modify their procedures in confirming documentation so they are clear through their process what type of implant is planned, boost versus full-dose implant.

This event is one where the dose delivered was 27 percent less. It's a little vague in the details to really be able to comment to you on what exactly happened, other than to say that there seems to be a lot of procedural problems at this site, because the licensee was cited for several failures, not developing proper written procedures, not doing proper exceptions, testing some computers, not properly

documenting post-procedure written directives, not doing an annual review of quality safety programs. It doesn't sound like they had much of a safety culture, but, again, details of the specific cases are not forthcoming, and they were requested to hire a medical physicist to audit their program in the future.

Another one, which is listed, again, in somewhat vague terms, but said that it was due to, "irregularities found in the licensee's practice." I don't know if it's related to my prior case presented, because they are from the same corporate entity but seem to be different sites within the same corporate entity. So, I don't know if the regulators said, all right, now that we saw a problem in one division of this entity, we are going to go visit the others, and then in another one they found a problem. That's a bit of interpretation on my part, but that may be the case; it's hard to say for sure.

In that event, they did find two specific medical events where the dose delivered was 37 percent of prescription and 67 percent of prescription. Both used palladium. But again, really can't comment much on the events themselves with this little data provided about the specifics of the events.

Here's one with D90. This again is a dose

parameter that is often used, but I'm not clear if that's really a regulatory thing, because although some -- many papers show D90 to be important, not every research study has. But in any event that was used in their report and was reported to NMED as 34 percent less of prescription, although it was later retracted. That with further investigation, I guess the regulator felt it was not an event. Anyway, this highlights the need for the rulemaking that we've been talking about for a while.

And again, one case where misplaced seeds resulted in a higher dose in the rectum by 61 percent. This is also a little vague, because that could be trivial, or it could be significant. 61 percent is only a percentage. If it was 61 percent of 1 cc of the rectum got 160 Gy instead of 100 Gy, maybe that doesn't matter. But, if it was 5 ccs, et cetera, you understand. So, it's a little hard to know whether this is really something that ought to be a medical event or not, but it was reported, and the licensee, essentially, said they could find no cause other than it's not an easy procedure to do, and there's some inherent uncertainties in there.

Moving on to Gamma Knife, and other .600. So, here we'll do the HDR, I apologize. And, so again,

not much of a trend really. I would say, perhaps, a slight uptick in HDR, but very -- I wouldn't really make anything of it. We'll go over the specifics of the HDRs.

One was a bust; nine were GYNs; one was a skin too long. And, conceptually or categorizing them, five had to do with wrong positioning of the sources, or the applicator in which the sources went, and three had to do with wrong reference length entered in the planning. Two were, it was, actually, the wrong patient's plan, presumably, two patients with the same disease getting fairly similar treatment, but still it's the wrong patient. And one was "a deficient treatment plan", again, what the deficiencies were was a little vague, and two machine problems due to some type of malfunction. I don't think we have more data on those two to know whether they are a common thread, unfortunately.

And, generally, the way these were dealt with were increased training or fixing the units or upgrading of units, implementing a proper timeout, verification of the site cylinder placement. This would be for, presumably, a vaginal case, that it's place correctly, and making sure that it's in the same position when you complete the treatment. And,

manufacturer notification, presumably, having to do presumably with one of the cases that we alluded to before.

In terms of Gamma Knife, so there were no regular Gamma Knifes, but there was one perfection event, fairly significant it seems. Systematic problem that occurred for eight patients, where the target was off by 1.8 millimeters. So again, depending on exactly what was being treated, that could be pretty significant. Those exceeded the prescription by 100 percent, and they implemented a new set of tests to verify patient positioning to prevent that from happening again.

Moving on to 35.1000 events. So these are, essentially, all microspheres this year. They are all microspheres this year. Radioactive seed localization, there were no events reported this year for that modality.

In terms of the microsphere events, so three of them were situations where microspheres were retained in the catheter, the tubing, the hub, the vial, and it resulted in under doses in the 70 to 60 percent range. Five of them were situations where small catheters were used, which led to microspheres being retained in the hub, and all these occurred at one

particular institution. We'll get into more detail in the next few slides on these.

One was just an incorrect set up of tubing, and really about tubing and catheter issues. One was incorrect tightening of the tubing, leading to a leak. And, one was kinking of the tubing. So, a lot of those -- all those, obviously, they are falling into the tubing and catheters, et cetera.

There were some other categories as well. There was a low flow to some small arteries leading to a decrease in dose from intended. There was one case -- well, I'll give you some more detail in a moment, where the stomach actually received a low dose, but still an unintended dose, and the infusion itself was discontinued because the shunting was going on, and the catheter, apparently, moved during a procedure when the fluoroscopy table was moved, and this wasn't detected. And this led to infusion of a significant percentage of the dose to the wrong vessel, which then went to the small bowel, rather than to the liver. And, presumably, they did not re-image after moving the table, and the corrective action was to do that in the future.

And, two others went to the wrong arteries. One was in the liver, but to the wrong artery, so it

was, therefore, the wrong lobe. And, the corrective action was to have an angiogram present, so you remember which side of the liver you are going to.

And one was there was an infusion into the kidney, to the artery feeding the kidney, the renal artery, instead of to the liver, and this delivered a very significant dose to the kidney.

This had been the first procedure done by the licensee, which as we all know, the first time you do something, typically, it's a set up for potential errors. They caused no damage to the kidney, but the "yet" is my editorial comment. That was a lot of dose to the kidney.

And, corrective action is to have a formal checklist, mapping of the images prior to procedure, analogous to the prior case, and making sure a second MD confirms the positioning of the kidney. That seems like a wise idea.

And so, two reported, actually, as underdoses, but then were later retracted with further investigation which revealed the correct dose. Again, more detail about like what was the -- why did one person think it was one, or what was the correction, not enough detail to be able to comment on that.

So, those were the TheraSphere and the

other brand. I'm blanking on the name right now. But that's the events for the year.

The last part is about other medical events that are more to do with transport and things like that, and there are a variety of these, and we've got the current year's events and then in parentheses last year's number of events, and similar to everything else, I would say there's no clear trends, just bouncing around in relatively low numbers, but considering the scope of these things.

So, there's some leaking sources. There's some lost sources in shipping. Thankfully, no category 1 or category 2 sources. Some shipping issues. And, what we've talk about here a couple years ago, landfill alarm issues.

Some occupational over exposures, no public exposures this year. No airborne issues this year. A couple equipment failures, some contaminations, record-keeping, no "suspicious" activities.

Cesium-137 is just isotopes that are used; you can see them here.

Lost source after procedure 10, lost/found, you see there a few of those, lost during shipment. The package was thrown away we didn't have

any this year. Theft, none this year as well, and a buried pacemaker. Okay. That should be our worst problem.

And, delivery to the wrong address, there were four, stored in unsecured area, one; accidents on the roads, none this year; shipping package issues; and there were no sources delivered to someone who is not approved. That's good.

And, landfill issues, you know they have been one in the past, and there are, again, a decent number of them, but I guess in the big picture, it's still not a huge number. And again, not very much from years past.

But, I guess only a few Agreement States actually report these, so, presumably, there are a lot more out there. And, why some states report these and some states don't I guess is worth a conversation. I don't know.

So again, pretty stable trends I would say. Nothing jumps out. There are a few patterns there, for example, in the microsphere arena there seems to be tubing issues as, you know, a significant reporting of these events are tubing issues, I don't know if that means we can send out an alert, or someone ought to tell people to be really careful about your tubing issues,

whether there's a mechanism for that, I don't know. But, that is one thing that stands out a little bit, and was a fair number, you know, that were within that space.

All the rest seems to be pretty much reading the written directive properly, following the proper procedure, being clearly documented, putting the decimal point in the right place. These are, you know, not really things I think that we can, it's part of being human beings and being flawed.

So, that really concludes my report. I'm happy to answer any questions.

CHAIRMAN ALDERSON: Thank you, Dr. Ennis. Yes, I have two questions, they are just clarifications. One is just a clarification.

On the slide that was about two slides ago, it's your page number -- it's this table, it's your slide number 36.

DR. ENNIS: Is that this one?

CHAIRMAN ALDERSON: Yes, that one.

DR. ENNIS: Okay.

CHAIRMAN ALDERSON: The other events, landfill. Down at the bottom it has these percentage numbers on each one of those reports from agreement states. Is that a misprint, or does that mean there were

18 such problems this year in Alabama, and 12 last year, or what's the percentage?

DR. ENNIS: I think it's the percentage of events reported by that particular state for the entire group. So, California presents 81 or 85, depending on the year presented, of all the events reported to NMED of a landfill type.

CHAIRMAN ALDERSON: I see. Okay.

DR. ENNIS: So, California seems to care about landfill events more, or has a lot more of them.

CHAIRMAN ALDERSON: Yes. All right.

MEMBER LANGHORST: Dr. Alderson, I'll say these are the ones that I could tease out that looked like could be from a medical type of issue.

CHAIRMAN ALDERSON: I see. Okay. Thank you.

And, I guess that we commented earlier on that very nice set of slides that just appeared about two days ago, and are these all -- those are all going to be updated by this year's report?

DR. ENNIS: Yes.

MEMBER LANGHORST: So, let me talk a little bit about that, because last year was supposed to be the first time I reported on that, and I apologize, I wasn't here. I really apologize that I wasn't here.

But, that spring meeting before that, the issue was raised that one of our former members, Ralph Lieto, used to do this presentation, and everyone looked at me like, why haven't you been doing this. I didn't know I was supposed to.

So, I think in the past, when Ralph gave those reports, he, typically, gave them when Dr. Howe did her updates. And so, what I'd like to propose is that I put together this new set of data and report it at the spring meeting with Dr. Howe, kind of get it out of the medical look at medical events, to just kind of update that.

And, hopefully, that I could work with Zoubir Ouhib to get him up to speed on it, so he can carry it forward after I'm off of the committee.

So, that's what I'm going to propose, and, hopefully, we can work that out.

CHAIRMAN ALDERSON: Sounds like a good plan. Does anyone else have a comment on that?

Thanks very much, that will be excellent.

DR. TAPP: Dr. Alderson, this is Katie Tapp. And, to respond to Dr. Ennis' comment about issuing a notice regarding tubing with the yttrium-90 event.

The NRC does have options to issue generic communications, such as information notices, to share

operating experience and events. If that is something we are going to identify here, we can look that and share that with industry.

DR. ENNIS: We think there are enough events that that would be worthwhile.

CHAIRMAN ALDERSON: Mr. Green.

MR. GREEN: Not, specifically, on the TheraSpheres, but for the Part 100 -- sorry, Part 200 and Part 300, radiopharmaceutical event that you mentioned in the beginning of your presentation.

Almost every other medication in the hospital, except radiopharmaceuticals, is now tending towards bar code bedside verification of accuracy of drug. And, nuclear medicine has always been a gap.

The Institute for Safe Medication Practices, ISMP, is propagating pushing this to be a standard of care. And, radiopharmaceuticals, at least through certain providers, are now barcoded for bedside verification. So, knock on wood, we might see a decrease in events related to radiopharmaceuticals if barcoding does catch on.

DR. ENNIS: Just for a licensee, what is required on their end? Do they have to buy equipment?

MR. GREEN: No, it's printed on the prescription.

DR. ENNIS: What's that?

MR. GREEN: It's printed on the prescription. So, it should interface with the barcoding technology you already use to give the patient a Tylenol.

But, nuclear medicine was a gap. Now it may come with, doses of sestamibi or medrinate would come with a barcode on the prescription.

DR. ENNIS: But, I think those barcoding things are for in patient.

MR. GREEN: Yes.

DR. ENNIS: So, what -- but, on the outpatient side such a system isn't in place. So, if someone was an outpatient in nuclear medicine?

MR. GREEN: Then they'd have to outfit themselves with barcode readers.

CHAIRMAN ALDERSON: A clarification, Mr. Green.

Is this only if certain suppliers are providing those doses from certain central pharmacies?

MR. GREEN: That's correct.

CHAIRMAN ALDERSON: So, if you are an academic medical center you have your own in-house group, this does not exist.

Dr. Langhorst.

MEMBER LANGHORST: And also, if you get a bulk dose, if you are proportioning it out to give to patients, you wouldn't have that patient's specific barcode. So, it would mean you would have to have barcoding, not only just barcode reading.

MR. GREEN: Right. So, it is related to the patient-specific unit dose.

CHAIRMAN ALDERSON: So, this may be a trend that's coming, but it's coming only in one part of the industry right now.

Other comments or questions about the medical events report?

Anyone from the audience who would like to comment?

MEMBER COSTELLO: This is Frank.

CHAIRMAN ALDERSON: Yes, Frank.

MEMBER COSTELLO: Dr. Ennis, I have a question for you to think about. Reflecting on what we heard in the previous presentations about their reporting systems, and noting that you noted some of our reports were lacking detail or maybe lacking depth on root cause.

Should we consider any recommendation on how the NMED reports are prepared, prepared and the level of detail that are in them. So, it makes our

analysis more meaningful.

DR. ENNIS: I think, certainly, that would be helpful. I guess I don't know like how you would create a language in the regulation that would, specifically, illicit enough detail, if it's not being provided, because this really comes out of the anecdote, the story as one of the speakers said before, really, what you get in the information is the narrative part.

I don't know that we could -- but maybe someone has an idea how to mandate a narrative that is rich enough for us to really interpret it.

MR. GREEN: I'd like to comment on that.

CHAIRMAN ALDERSON: Mr. Green.

MR. GREEN: Yes, I'm thinking of, you can either write your own procedure to do dose calibrator testing, or you can say I'll follow the guidance provided in, I believe it's, Appendix O. So, you can either take the easy path, or do it yourself.

There may be an opportunity here to write a couple of examples of ways to do it, so folks will have a good example of how to provide all the details we are looking for, so we can, actually, make sense of an event.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: On the NMED reporting, this is either NRC putting in that data or agreement states putting in that data. So, it's the same kind of issues that Ms. Elee had brought up about CRCPD reporting.

And, I have a question probably for NRC staff, I know in looking at NMED data, which is very nice that our committee has access to that, but the public does not, that there seems to be agreement states that never put anything in there.

And so, I don't know what the requirement is to report NMED incidents and have it be in there by the various agreement states.

CHAIRMAN ALDERSON: Dr. Howe has a comment.

DR. HOWE: The matter of compatibility for NMED is a C, which you discussed in length with the medical reporting part of it, and that means you have to meet the essential objectives, but they don't have to be identical.

I did want to say that the requirements of what needs to be reported are included in 35.3045, and it's a brief description of the event, why it occurred, the effect, if any, on the individual, and what actions, if any, have been taken.

You will find that in many cases if it's

an NRC report, you will see a lot more information, because our inspectors will go out and give an inspection report, put more of their information in.

The agreement states had a more mixed response on the richness of the information that is provided, but they have to provide this minimum information.

CHAIRMAN ALDERSON: Yes, Doug.

MR. BOLLOCK: I can address that a little bit more. So, the states, by agreement with us, there are state agreement procedures, they will, in a certain amount of time, when it's in an agreement state, the event happens in an agreement state, they will report to us, and then put in NMED at least those -- or what's required in our regulations, or pretty close to that.

And then, as Dr. Howe was saying, NMED reports then get updated after inspectors who are filing inspections occur, they -- that's where they may get the probably causes or root causes. And so, it does vary on how much follow through is done, at what point that was, and then there will be updates periodically in NMED.

You know, our inspectors are good about updating it after their inspection, after they have completed the report and their evaluation. And, the

states, some of them are very good about that, others, as you alluded to, are not as good.

So, yes, there are some disparities in the data in NMED.

CHAIRMAN ALDERSON: Yes, Dr. Langhorst.

MEMBER LANGHORST: I want to follow up on one thing that Ms. Fairobent brought up, in that on the NRC's event reporting website, the agreement states do put in their events. And so, there's not anonymity, necessarily, if the facility is named. But, some agreement states don't name the facility.

And, as Ms. Fairobent brought up, you can, for NRC inspections, look at inspection reports and kind of tease out the information. But, those reports for agreement states aren't available. And so, again, there's just very little follow up information you can get publicly.

MR. COLLINS: So, this is Dan Collins. Just wanted to respond on that.

The few states that do provide some level of anonymity to their licensees, it's because they have state laws in place that are associated with that. The remainder of the states, most of them have some form of a Sunshine Act that requires the information to be public, similar to Federal regulations.

CHAIRMAN ALDERSON: Frank Costello, you are, obviously, our states' representative. Did you hear this discussion? Do you want to make any comments?

MEMBER COSTELLO: Yes, thank you.

There is variety among the states, and this reporting system, you know, the medical event reporting system, has a huge purpose, which is to, you know, identify cause of medical events and share it with community. Ultimately, the goal is for the patient's safety.

The more, the richer the data is the better. Something that, perhaps, could be considered would be that if the states provide information and the NRC reviews it, there could be a dialogue between the NRC and the states maybe to tease out a little more information that the state didn't include the first time.

You know, there is, certainly, variety among the states on this and on every other issue. But, I think if there was continued dialogue between the NRC and the state when the reports comes in, that variety could be reduced a little bit.

CHAIRMAN ALDERSON: Thank you, and Dr. Langhorst and Dr. Ennis then will comment.

MEMBER LANGHORST: Sorry, and I want to follow up, too, that in the NMED data there are, is it quarterly reports that are published, or annual reports.

DR. ENNIS: Annual reports.

MEMBER LANGHORST: Yes. But, that few -- I can't remember now if they are anonymous or they do name facilities.

DR. ENNIS: They do not.

MEMBER LANGHORST: They do not. So, that is publicly available, but again, any details, there are, I'm going off of memory, there are details on some of the events, but those are mainly NRC type events.

CHAIRMAN ALDERSON: Dr. Howe wants to respond to that one.

DR. HOWE: Well, also in response to a similar question earlier, we are starting to --

MEMBER LANGHORST: We cannot hear you at all back here.

DR. HOWE: Okay. In response to that comment made earlier in previous ACMUI meetings, we are beginning to put together our slides that we present in the spring to give the public an idea of what the medical events are. We are not giving names of licensees at that point, but we are giving a short

description of what the events were.

And, the other pointed I wanted to make is, when you do your NMED reports, there is a short report, and it's the short report I provide to you at the spring. And, one of the reasons I developed that one was at the bottom there are references. And so, if you believe you need to see those references, we can go back and ask for the inspection reports and enforcement reports and those things that are referenced there, although many of them are very limited.

MEMBER LANGHORST: And, just one more point for our new committee members. NMED does not mean it's on medical events. It stands for nuclear material event database. So, it isn't just medical, it's all nuclear materials. So, don't be fooled by the NMED acronym. I was for many years.

CHAIRMAN ALDERSON: I think Ron Ennis has the next comment.

DR. ENNIS: Two comments. So one regarding this, and again I don't know the mechanisms, but I would endorse what Mr. Costello said, that NRC would encourage a more interactive process and a review as NMED reports come in, and a determination of their adequacy. And, if not, really reach out and get that information, so when we do this it's more meaningful.

I would say 10 to 20 percent of these cases really were not meaningful. And, if that becomes an operating procedure, then they can improve the quality of what we do.

Along the same lines, even if it's Category C, the disparity which states are reporting I think needs to be addressed. I think ongoing dialogues with the states that are not reporting, they can't not have the same proportion of events as the other states with the number of, you know, radioactive fields being used. It's extremely unlikely.

So, there's an issue there that I think needs, you know, some kind of dialogue between the specific agreement states and the NRC.

Then, I would like to ask that what Dr. Tapp suggests should be done, but I don't know if all of us feel the same, to, actually, send that with some kind of alert or whatever it would be called to users of the microspheres about tubing issues, because I think we see, I don't know if it's about half of the events, or about tubing issues. So, we might as well let people know, pay a little more attention to the various tubing issues in some non-punitive but educational manner.

CHAIRMAN ALDERSON: Right, and I think that does go along with the earlier session. The trending,

if we and the NRC find trending, it would be very useful to communicate that trending to the user community so they could be on alert.

Dr. Metter, did you want to comment?

MEMBER METTER: No, no, I totally agree with what he was saying.

CHAIRMAN ALDERSON: She did not. I'm sorry. I misinterpreted yes.

Dr. Bollock, did you want to comment?

MR. BOLLOCK: I was just going to say, if we let Dr. Palestro say, then Mr. Collins and I can address some of these and speak a little bit more.

CHAIRMAN ALDERSON: All right. Chris?

MEMBER PALESTRO: Yes. Whenever I listen to these reports, and look at the slides, I always try to figure out what I can learn from them from the nuclear medicine standpoint to take back to my own division, to try to improve things or make sure that we have things in place.

And, in thinking about this, particularly, the nuclear medicine section today, it seems that although the data is somewhat limited a lot of the errors can be attributed to procedural failures.

CHAIRMAN ALDERSON: Yes.

MEMBER PALESTRO: And, I think that this is

the type of information that we can bring back to our Society meetings, without going into specifics, and merely identify these are the types of things that we see, and when you go back into your practice you can review them and see whether or not everything is in order, or you feel that you can make improvements.

CHAIRMAN ALDERSON: Not only review, but, perhaps, preemptively teach about these procedures, and make people sort of relearn them periodically, to make sure that they know what they are doing, for example. That's great advice, Dr. Palestro.

MR. BOLLOCK: And so, we can address some of those. The first thing I'd start with, if ACMUI has a recommendation to us to do some sort of generic communication on the tubing issues, we can do that, actually put a note as that being a possibility. You know, it's fairly easy for us to write an information notice or some sort of generic communication and get that out to licensees, and also to the states.

CHAIRMAN ALDERSON: Good.

MR. BOLLOCK: So, that's something we can do.

MS. HOLIDAY: Doug, before you continue, this is Sophie, may I ask if that is an official recommendation or motion put forth by the committee so

that it may be captured on the record?

CHAIRMAN ALDERSON: Okay, so let's make this -- is there a motion to that effect?

So moved.

Is there a second?

MEMBER COSTELLO: Second.

CHAIRMAN ALDERSON: Fine, there's a second, and then is there any further discussion of this motion?

Yes, Dr. Dilsizian.

DR. DILSIZIAN: Ron, were the tubing issues, do you think, manufacturer problems, or is it kinking, they are not tightened right? We don't get that data, right?

DR. ENNIS: Right.

DR. DILSIZIAN: So, it's tough for us to really say there's tubing problems without having details data.

DR. ENNIS: Well, I guess you could -- I think you could say, you know, just pay attention to tubing, it could be human, it could be manufacturer, but just a heightened awareness to make sure everything is fitting together, and then you'll figure out, oh, I haven't been doing this right, or, oh, this tubing stinks, I need a new company.

CHAIRMAN ALDERSON: Mr. Green.

MR. GREEN: And, there are two manufacturers, is it fairly equal between the two, that it could be globally for the procedure?

DR. ENNIS: That's my impression. We could jump back if we have the time, but my impression was fairly mixed between the two. So, there were six SIR and eight TheraSphere, let's see, there was about 12 patients overall. It might take a little work to go through, I don't know if you want to do that. But, my impression was that it was pretty split.

CHAIRMAN ALDERSON: Other comments? There is a motion on the floor.

Dr. Langhorst.

MEMBER LANGHORST: Would it be more meaningful if the ACMUI encourages the manufacturers to look at this, because I don't think we have enough data to put together an information notice. And, I'd hate to put out many information notices, because that dilutes the importance of those, when we don't have the full information, but to encourage the manufacturers to look into this, and maybe even provide us with something to say that this is their view on that problem.

CHAIRMAN ALDERSON: Mr. O'Hara wants to comment on that.

MEMBER O'HARA: Yes. The manufacturers are regulated by the FDA. And, we are encouraging the manufacturers to look at these issues, these kinking issues. In some cases, kinking or a physician uses a different catheter.

I think at least one of the -- actually, I think both of the providers, actually, have their own catheter. So, the FDA is talking to the manufacturers about the catheters.

MR. BOLLOCK: If I can address this. Just a few things, but my staff, if we were going to develop an information notice we would look and try to get as much detail as we could in certain cases.

And, it could be just as generic and simple as, there have been a number of cases, you know, and give a couple of examples.

So, yes, just be mindful of that. And, a lot of times that is -- it can be as simple as that. It's just an information notice, just awareness to licensees and the public and the other regulators. So, it could be that simple.

So, yes, we don't, necessarily, have to -- I mean those are other options, you know, we wouldn't have to do that in order for us to develop and send out an information notice.

CHAIRMAN ALDERSON: And, the very knowledge and exchange of information, such as we just had between the representative, Dr. O'Hara from the FDA, and between the NRC, it allows the two agencies to see that this is happening on both sides, and that facilitates, you know, getting information out.

MR. BOLLOCK: Yes, if it was a device issue with the tubing itself, deficiency there, yes, it would likely fall under FDA, or, you know, we have Part 31 or something else, if it was a radiological safety issue with that.

But, we can do it independently. It can, like I said, we would -- my staff would look into these cases and get as much information as we have.

CHAIRMAN ALDERSON: And, the idea of providing an alert is the key issue.

Now, we do have a comment from the audience here.

MS. BLANKENSHIP: Bette Blankenship, AAPM. Thank you, Dr. Alderson.

We also find, because we are very active in administering MicroSpheres.

We also, not just the tubing, we also at times have residual MicroSpheres remaining in the hub of the administration device. So, I think a generic

message of we are having, you know, a number of reported cases where the spheres are not delivered for whatever reason.

So, I think if it is generic, that it would count for both of those.

So, thank you. I think that's very good.

MR. BOLLOCK: Yes, and we could cover both of these issues in one generic way.

CHAIRMAN ALDERSON: So, are there further comments on the motion, as I will say as amended by the information that's been provided by the interim speakers here?

Further comments? Hearing none, let's vote on the motion.

All in favor?

ON THE PHONE: Hello, aye.

CHAIRMAN ALDERSON: Opposed?

Abstaining?

MEMBER LANGHORST: I'll abstain.

CHAIRMAN ALDERSON: One abstention, but it carries. Two abstentions, I'm sorry.

DR. ENNIS: No, no.

CHAIRMAN ALDERSON: No, you'll support it. You are opposed.

DR. ENNIS: No, no.

CHAIRMAN ALDERSON: I'm sorry. This is Dr. Alderson, I'm sorry I didn't go in the right direction.

So, everyone is in favor except there is one abstention. Thank you very much. And so, the motion carries. Thank you.

MR. BOLLOCK: Also, to continue on, some of the other things you were discussing with agreement state information, or, you know, put into NMED, we do have regional state agreement officers who, if there are events reported from the state, they will -- there are primary -- NRC is the primary point of contact with our counterparts in each state, and they, typically, do, and they will follow up with each -- with the state if there was an event there to try to get that information.

So, there's that kind of on the day-to-day basis, that encouragement, and that communication, to get the feedback. Again, they are independent regulators, there's only, you know, we can encourage each other to get as much information and, you know, especially, getting more information is better for learning those -- you know, the root causes or what can we get out of that based on the information they've put into NMED.

So, we do, you know, on a day-to-day basis

we do that.

MEMBER COSTELLO: This is Frank. Can I comment on that?

CHAIRMAN ALDERSON: Please.

MEMBER COSTELLO: As you heard from another speaker, an earlier speaker from the panel, root cause analysis is a skill that's not always easily acquired. And some states, small, some states are well developed doing root cause analysis, and some states not too much.

Perhaps, the NRC, when they get the report from the state, look at the root cause analysis and consider whether the state could be given a little more help in doing this, because remember the presentation we had before, sometimes those reporting people are assisted and they can get into the real root cause. Otherwise, often it's done by your operator, or something like that, where you are not really getting the root cause, which could be a training issue, or it could be an issue where there are too many people -- too much is trying to be done in a short period of time because of peak workloads and that kind of thing.

So, perhaps, they, actually, consider giving assistance to the states as needed to get the real root cause, because not every state is willing for them to get the root cause.

CHAIRMAN ALDERSON: I think, perhaps, one of the issues you may want to clarify, Frank, is what assistance means. That could be the NRC providing some advice, or it could be something much more than that. What are you, actually, aiming at?

MEMBER COSTELLO: Yes, I think most of the time it would be advice, have you considered this, have you considered that? I don't think many states would want the NRC to take it over, but I think if they gave them assistance by advice on how to do the root cause, I think that might help.

CHAIRMAN ALDERSON: Would the NRC like to comment?

MR. COLLINS: Yes, so this is Dan Collins. Thanks, Frank.

So, we do have protocol in place where if a state feels like they need assistance that they can request it and we'll provide it. There's also, you know, root cause training that we could, perhaps, provide to the various states. So, there are a number of avenues with respect to how we might be able to provide some assistance to the states.

Also, we have had an effort ongoing for a couple years now for doing training for the agreement states relative to the NMED reporting, and that's

something that our staff, in concert with the contractor that administers the database has been performing. But again, that's at the state's request, it's not mandatory.

CHAIRMAN ALDERSON: Dr. Langhorst.

MEMBER LANGHORST: Mr. Collins, is there any group in NRC that focuses on root cause analysis specific to medical events?

MR. COLLINS: Well, that would be Doug's team.

MEMBER LANGHORST: Okay.

MR. BOLLOCK: Yes, it would be us. That would really fall on us, and we do have -- you know, there are -- there is, for NRC inspections we do have root cause training classes available for the state, being available to the state. They are available to state personnel as well.

I'd have to look at their specific qualifications if that's available. I know I have seen state represented when I took it years ago.

MS. ELEE: I've been there.

MEMBER LANGHORST: I'd just like to point out that medical use is different.

MR. BOLLOCK: Yes, and I've taken the classes, as Jennifer has, yes. It is, a lot of times,

the focus is, primarily, on reactors, a lot of --

CHAIRMAN ALDERSON: Jen, microphone.

MS. ELEE: Yes. My comment was just that I have attended the root cause analysis class. I, actually, think it's a very good class of the many NRC classes. But, it is not a lot of medical information and medical is very, very different.

So, it may be that like we talk about training, it's medical training on root cause analysis that we need to consider.

MR. BOLLOCK: Yes, the class, they use different examples, not, necessarily, even nuclear in some cases. So, they do try to broaden it when they give the examples. But, it's more how do you figure out a root cause, or something -- in some cases we have a class on how to review root causes, and they give examples that are not, necessarily, just reactor, you know, they use different types, and even other -- I've seen them from other, like DOT, and examples like that.

So, they do try to broaden it. It is more focused on root cause. But, specifically, did they have any specific examples of medical in the class that I took, they did not. And, maybe there are some contractors that do it, but again, they do broaden it, and the focus is root cause, not, necessarily, the

technical part.

CHAIRMAN ALDERSON: Are there any other comments people would like to have or questions for Dr. Ennis on his report?

Dr. Suh.

MEMBER SUH: Just a question. I see part of this reporting structure is to learn, and also to come up with best practices. So, is there a possibility for -- right now all these reports are divided up into Part 200, Part 300, 500, or 600, 1000.

What I would find meaningful is that if there's a way of trying to figure out, is there a common theme through all of these reports? And, what I mean by that is, when I look at the -- listening to Ron's presentation, many of the errors are just because time out wasn't done. And, I think we see a trend that time outs are not being done on a routine basis. That's something that, perhaps, the committee, NRC, could say it's something that we should really take seriously, I mean because part of this is the right patient here from the right location, and, you know, many of the reports are because just simple base procedures weren't done. I think sometimes you just forget, you get in a hurry and you forget, yes, you have to always identify they are treating the right location, right patient on

the table, et cetera.

And, I think when we go through these reports year after year, but I'm not sure if we're focusing on what is the true root cause. At least for me, the Section 700 there's some patient identification which just wasn't done properly. I don't know if there's a way to categorize the incident. At least you get the trend, shows a trend that we are not doing time out as well as we should, or is training not as robust as it should be.

CHAIRMAN ALDERSON: Thank you.

Other questions or comments?

Hearing none, I believe that we are ready to --

MR. OUHIB: This is Zoubir, can you hear me?

CHAIRMAN ALDERSON: Who is this, yes?

MR. OUHIB: Zoubir.

CHAIRMAN ALDERSON: Please. Please, speak up.

MR. OUHIB: My apology for joining a little bit late, but I've been listening to some of the conversation.

Now, on the SIR-sphere and the TheraSphere, I just have a comment on that, that I think somebody made a statement on that, is that it would be

extremely valuable to have more data from both manufacturers, and find out exactly how many of the -- how many people, you know, how many users, actually, experienced the issues. And, what's the total number of users that we have.

The point I'm making here is that, I know for a fact that there are some institutions that did not experience these tubing issues and all that. So, therefore, is it a training issue or is it a user issue, or what is it exactly?

And, I think that will help us probably get a little bit more understanding about that. And, perhaps, provide some valuable lessons, or, you know, remedies, or what not.

CHAIRMAN ALDERSON: Thank you. Thank you, Mr. Ouhib.

Any other questions or comments?

Hearing none, I think we are ready to bring -- we have one more comment. Yes, Mike Fuller.

MR. FULLER: Just a real quick question before we break.

Sophie, could you read back what the actual recommendation is that just -- or the motion, what the motion was, because at one point I heard that staff should look into this and see if generic communication

is appropriate. And then I think I also heard that we were, actually, receiving a recommendation that we issue some generic communication.

So, could you just clarify that for me, please.

MS. HOLIDAY: Sure. So, the recommendation that I have written is that ACMUI recommended that staff issue a generic communication regarding tubing issues (kinking, connection, et cetera) during the administration of Y90 MicroSpheres brachytherapy.

Is that appropriate as captured by the committee?

CHAIRMAN ALDERSON: Yes. We are all nodding our heads, yes.

But, there are people now that want to comment.

MR. BOLLOCK: Well, the tubing and hub issue.

CHAIRMAN ALDERSON: The hub was in the et cetera, but, yes, you can add that specific, yes.

So, Mike, does that answer your question?

MR. FULLER: Yes, thank you.

CHAIRMAN ALDERSON: It does.

Are there further questions before we draw

this session to a close?

Seeing none, I think we'll close this session, and we are adjourned for lunch. And, we'll be back at 1:00.

(Whereupon, the above-entitled matter was recessed at 11:30 a.m., and will reconvene this same day at 1:00 p.m.)

DR. ALDERSON: Well, we're ready to start the afternoon session. We're going to continue our discussion of medical event reporting, and be led by Dr. John Suh.

MEMBER SUH: All right, good afternoon. So I'll be reporting on medical events reporting for all modalities except permanent implant brachytherapy. I want to acknowledge the Subcommittee members, Ron Ennis, Vasken Dilsizian, Chris Palestro, Pat Zanzonico and Zoubir Ouhib.

So the Subcommittee's charge was to propose the appropriate criteria for medical event by reporting other than permanent implant brachytherapy, and on March 17th of this year, the Subcommittee's initial thoughts of the definition of medical event reporting for all modalities except permanent implant brachytherapy were presented.

Recommendations from the March 2016

meeting were that the medical bench reporting shall offer identification of a medical event and provide a mechanism to discuss how to avoid and reduce the likelihood of such an event, and also that the definition of a medical event needs to be broad, simple and consistent, so reports can easily be prepared by authorized users, evaluated by regulators and process focused in order to limit ambiguity.

In addition, the part of the definition based on "unintended permanent functional damage from an organ or physiologic system as determined by a physician" needs reconsideration. Also, we felt that the creation of a subsection within the current framework of medical bench reporting be considered to allow for new radiation oncology modalities or prescribed dosage rate and volume routed to a point. Now any proposed change should not overly be prescriptive and encroach on the practice of medicine.

So in terms of the ongoing discussions that we've had, we discussed current any reporting criteria under 10 C.F.R. Part 35.3045, and we've discussed various scenarios where the medical event criteria may be somewhat ambiguous and maybe require additional modifications.

Given the advances in radiation oncology

in particular, that site shifts can actually result in significant dose of nearby tissues and/or organs, so that prescribing to a point is really not relevant to how we prescribe in radiation oncology in particular.

So one of the discussion items that we had was that current radiation oncology plans are not prescribed to the point but usually to a treatment site. So the Subcommittee felt that the current ME definitions for radiopharmaceuticals are sufficient. So that should not be a part of the subcommittee, but that we should devise a definition for 2-D and three dimensional conformal radiotherapy, intensity- modulated radiation therapy, which is IMRT, SRS, which is stereotactic radiosurgery, SBRT, which is stereotactic body radiation therapy, low dose rate, high dose rate brachytherapy and intraoperative modalities.

During our discussions, we also felt that this language "unintended permanent functional damage to the organ or physiologic system, as determined by (reading)" in Section 3(b) of 35.3045 and not be revised.

So the medical event criteria would need to cover these modalities, high dose rate for all body sites, Gamma Knife, low dose rate, temporary brachy

implants and intraoperative modalities. So in terms of the main modification that we focused on was really the -- if you look at 1, Part 1 and Part 2, is that the original definition was total dose to -- differs from a prescribed dose by 20 percent or more.

So what we discussed was adding the phrase "treatment site." We actually went back and forth on whether or not we should do the definition of a target versus a treatment volume versus treatment area. We ultimately decided that treatment site would best fulfill what we wanted.

Also we also talked about having 80 percent of that treatment site, because of the way radiation planning is done today with the various modalities, be part of the definition. So the recommendation was that the total dose of 80 percent of the treatment site differs from the prescribed dose by 20 percent or more.

So again, the main difference is that 80 percent of the treatment site is the big difference. Then for single fraction treatment, it's 80 percent of the treatment site differs from the prescribed single fraction dose for a single fraction by 50 percent or more. The treatment site would be defined by physician and could be referenced by the signed treatment plan. Just trying to minimize ambiguity from the regular

standpoint.

So again, the big part of our discussion was how to word that section of treatments, and we ultimately decided on treatment site. The hope is by defining medical event by use of treatment site that it will be easier for the licensee to determine if an ME occurred.

Also, hopefully it will be easier to inspect and regulate, will better protect the public, and facilitate programs, procedures and education to prevent future events. Since the delivery systems and risk are different for each of the modalities, we felt that a specific medical event for each modality may provide some advantages, but we felt that overall that a modality-specific ME was not advisable, and that their classification of non-selective internal radiotherapy, non-Viewray and non-radiopharmaceuticals using the definition of treatment site as part of a medical event reporting structure.

So the current recommendations are that we use the current definitions for the permanent implant, that we use the current 35.3045 definition for radiopharmaceuticals, and for treatment sites that utilize 2D, three dimensional conformal radiation

therapy, IMRT, SRS, SBRT, low dose rate and high dose rate brachytherapy interactive modalities, that we utilize the definition of treatment site to help clarify what would be encompassed for it being a medical event.

The subcommittee believed that the creation of a treatment site within the current definition be considered to address the new radiation oncology modalities that prescribe dose to a volume. But I think historically what we've thought of as a point to take into account the newer modalities that we have available today.

DR. ALDERSON: Okay, thank you Dr. Suh. Next, we're clearly going to hear from the radiation oncology segments of our team. So Dr. Ennis, would you like to comment on this?

MEMBER ENNIS: John described well the thinking on the Subcommittee. We participated in the discussions and the key, you know, to step forward is to start talking in volumes rather than just dose, which is not really so meaningful anymore in terms of how we do it.

We have this ambiguity of occasionally licensees thinking they have an event and the regulation saying they don't and vice-versa, and

wanting to kind of follow the general rubric that's already been established about criteria levels seemed that this was a good way to do it in terms of defining, just defining as a treatment site the volume that we're talking about, and then having a high proportion of that as if a dose variation to that treatment site in a high proportion of that volume of that site, and that would rise to the level of a medical event.

So I support, and that was the recommendation we put out here and I think that's it.

DR. ALDERSON: Okay, Laura.

MEMBER WEIL: (off mic)

MEMBER SUH: Yes. We went back and forth with that a little bit. Let me just go back that definition. So there is -- when we do any type of radiation procedure, there are some unintended things that can happen as a result of actual treatment. So this phrase we felt encompassed that in some situations you may have unintended damage to the organ or the physiologic system as determined by the physicians.

So we wanted to just give that leeway in terms of what constituted an unintended event. So we actually played with the verbiage a little bit, trying to change some of the words around. But we felt that this actually best encompassed what we wanted as part

of this definition.

MEMBER WEIL: So you -- the group as a whole did not feel that permanent functional damage was problematic in terms of there can be serious temporary functional damage as well. I mean the patient might recover some function in a limb or in skin or in something, but it would still be an unintended event and still be significantly harmful to the patient.

MEMBER SUH: I mean that's a possibility. Again, for this, in terms of calling it a medical event, we decided to keep the word "permanent" in there.

DR. ALDERSON: Dr. Dilsizian.

MEMBER DILSIZIAN: Laura, if you remember, we had this discussion previously on the committee, and if I want to read back to you, what we decided at that time was -- it's in Item 12.

This is in October 2015, that we said unintentional treatment outcome due to an anatomic or physiologic anomaly falls into the category of the art of medicine practice. Remember that statement, provided that the standards of medical practice was met.

So I think if you think about this, it's the same thing. It's unintended permanent functional damage is unintended, meaning it could be anatomical

variation, some physiological variation, something that the physician didn't, you know, perceive or couldn't prevent and didn't practice outside the medical practice to create that damage. I think --

MEMBER SUH: And that's how we interpreted it.

MEMBER DILSIZIAN: Yes.

DR. ALDERSON: Just for clarification, as I understood these last comments, the issue is the word "permanent" up here. So if the patient gets a dose to the bowel that's outside the treatment area and the patient has serious, you know, you can imagine complications, and that goes on for an extended time, could interrupt their work, could change their lifestyle.

But eventually, it clears up she's asking, I think, that would not be a medical event. Is that right?

MEMBER SUH: I mean there are some situations. Even in the best planned out therapies, you can get complications as a result of the treatment. So I think the use of permanent is to rise to the occasion of being called a medical event.

DR. ALDERSON: Dr. Ennis.

MEMBER ENNIS: I guess -- first of all I'm

saying it did not meet any of the dosimetric criteria, right. So it was not that 80 percent of the volume did not get the dose. So that didn't happen. So kind of execution-wise, it's not at the level of a medical event. But we want to have this other catch-all, should I stop? Yeah. Donna-Beth seems to want to --

DR. HOWE: So this is just a point of clarification. The document says Section 3B. It is not Section 3B. It is Section B. It happens to come under 3, but Section B is only referring to when you have patient intervention. So in your discussion, you're kind of applying it to a medical criteria in normal practice.

But this section B only addresses patient intervention. So I just want to make sure that as you're discussing this, you are understanding that in our regulations.

DR. ALDERSON: I'm sure that the committee wants it to be in the correct section, whatever that section is. If Dr. Howe is correct, I'm sure the committee would agree that you put it in Section D as in Dog. That was – if that was where it belongs.

DR. HOWE: I think that the confusion is that B comes right after 3, and so people thought it was 3B, and in fact it's B because A in the beginning

talks about regular medical events and B only talks about patient intervention.

DR. ALDERSON: Okay, very good. Well, we'll see that it's repositioned in the correct place. Yes.

MEMBER LANGHORST: I wanted to come back to the volume versus point. In order for inspectors to identify, it seems like this might require new regulations and what you document for a written directive, to require that this information be put down some place with assurance that the circumstances of the planning are the same as the circumstances of the evaluation post-treatment, to show that 80 percent of the target area is not different than 20 percent.

I can't even say it in the correct way, but you understand? As an inspector, I mean as I have to look at these things, I'm not sure I'd know how to look at it. I know that's one of your intents, to make sure that the inspectors can recognize it too. So did you talk about that aspect of how this would be done?

MEMBER SUH: So I think a lot of it -- so some of this is going to be actually on the treatment team, on the physician. So if, for instance, I am doing a stereotactic treatment or vertebral body that's supposed to be a T-12 and I treat T-11, then that's a

medical event. I have mistreated that patient. Clearly, 80 percent of that volume did not get the does that I intended to receive.

That's something where I would voluntarily say that was a medical event. So I think part of it also needs to be on the physician and the physicist to report that as well. I mean in terms of treating, you know, the other definition of terms of like wrong site, wrong patient, wrong -- I mean all those statements say it.

So this is really trying to -- because depending on where, and if you're treating a volume and if there's a point that's more peripheral versus more central, you can have a definition be somewhat more ambiguous, and we want to try to make it more clear now. You could argue is 80 percent the right number, you know. Is there a paper that says sort of 80 percent, 90 percent.

But we felt it needed to be -- the majority of the body needed to be treated with whatever technique that you're using. It really more applies to the radiation technologies, which actually have this very sharp dose gradient. We want to make sure it's encompassed within the treatment area.

MEMBER LANGHORST: But where would I find

that as the inspector? Am I only able to be told it's a medical event and I would never have an opportunity to identify it if you chose not to report it? I mean how does it work?

MEMBER ENNIS: So I guess right now, how do you know what part of the written directive of the prescription is your source of information about what I was intended to treat?

MEMBER LANGHORST: I agree. Sometimes an inspector can't without the licensee, and that is -- that's --

MEMBER ENNIS: So is the question how is this changing? I mean what's required right now? I mean in the normal practice of most practitioners, we write in the prescription what it is that we're trying to see, and that's what we have in mind when we say the treatment site. But regulatory-wise, tell me what right now happens that allows you to decide whether the dose was okay or not?

MEMBER LANGHORST: And so I'm just trying to get to your point that you're trying to make this better, and so I'm not sure I understand how it's better. I'm not arguing that we have a perfect system now. But yeah, that's my question. I'm not certain what needs to be done in order to document this so you

can show we did this evaluation and this is what it was, and here it is on this piece of paper or this database or whatever.

MEMBER ENNIS: I think the words it's in the treatment plan, but maybe that wouldn't -- can you go back John to the slide?

DR. ALDERSON: So we have a comment from NRC then here.

DR. TAPP: Dr. Suh if I may --

DR. ALDERSON: You need a mic.

DR. TAPP: Okay, thank you. I'm an NRC staff member on the subcommittee. One of the things when you give this total dose to 80 percent, you're allowing the inspectors in this review to start using the standard dose volume histogram curves that are used generally in practice of medicine.

You're talking about we could actually start using these and you could show that to inspectors and we could actually use this as a line you draw. It's an easy shift, then, to see that 20 percent. So it's actually a little bit easier to actually identify medical events.

MEMBER SUH: It's more quantitative than we have now. So yes, so I agree. It is more quantitative, because you look at the graph and say well

I'm off by whatever, 20 percent, 30 percent.

DR. TAPP: So you can actually use -- you can actually use graphs, that we could start to show inspectors on how to read one, and like today, where different people can prescribe it different ways and evaluate it in different ways, okay. If that helps.

MEMBER LANGHORST: So I'll ask Dr. Tapp. Do you then think that there needs to be changes in not only the medical event reporting criteria, but what needs to be documented on the written directive, to say this is the data that -- to make it consistent, so that you can show that? That was my question, of how do we do it?

DR. TAPP: Yeah. If that would be the recommendation. We'd have to look at it as a whole if we actually went forward with this, yes.

MEMBER SUH: And I agree. This is not a -- I mean we've had a lot of discussions about how to define a medical event and it's a little bit of a moving target, and we wanted to at least just to present to the Committee that there's always one thought of -- again, we want to use treatment site.

MEMBER LANGHORST: Right.

MEMBER SUH: You know, because I think that's a big move trying to going through. Right when

we were going between do you call it a target, a treatment volume and ultimately we decided target site was best for the patient. The last sentence on this particular site, the treatment site's defined by the physician. The physician has to define what that treatment site is going to be.

So that's really going to be on the physician to decide that, and then the treatment plan would be something you can refer to, to say that you actually treated the patient. So obviously if I were to treat, I'm going to use Gamma Knife as an example, I'm supposed to treat a right-sided brain lesion, but the plan clearly shows I treated the left side. I mean that's an ME.

MEMBER LANGHORST: Right.

MEMBER SUH: And the purpose of using this 80 percent definition is that if the treatment plan shows that I am off by more than 20 percent for that one treatment site, at least that's a cut-off, that we at least are proposing to call it a medical event for that treatment.

MEMBER LANGHORST: And I am fully supportive of that. I just wanted to know how you do it so that the inspector can see it, that --. Then I had one other question.

DR. ALDERSON: Sure.

MEMBER LANGHORST: Did you review, also consider all of the 35.1000 uses? You said Gamma Knife, but Perfexion is under 1000. So I assumed that's kind of included, and then let me think if there's anything else. I guess there's no --

MEMBER SUH: Right. So this, so as part of the definition --

MEMBER LANGHORST: You said not Viewray. I know you cut --

MEMBER SUH: Right, not Viewray, and also again, right now the Perfexion, as you know, is under 35.1000. So it's really meant for the non-Viewray, non-SRTs, because we felt that the current definition, KSRT that we've talked about as a group was sufficient, and we also felt that the radiopharmaceutical definition, the current definition as it stands now is also sufficient as well.

So it's really to address more than radiation oncology-specific brachytherapy, non-permanent implant brachytherapy modalities with this.

MEMBER LANGHORST: And so then that would leave out the microspheres, which are brachytherapy? But they're permanent. Okay, thank you.

MR. OUHIB: Hello, this is Zoubir.

DR. ALDERSON: Yes, please Zoubir.

MR. OUHIB: You know, I think we forgot the purpose of a quality management program, which is really -- I mean the intent there is to review post-treatment, if there was any possibility of a medical event, and if so, that's when you document that. So the answer to your question as far as the state inspector or the NRC, whatever, the first question is okay, well can you share with me your quality management program, and have you had any medical event and what is the outcome that's documented when you do a post-implant review basically, to determine whether there was a medical event. But that documentation is available from the management program.

DR. ALDERSON: Understood.

MEMBER LANGHORST: Yes, this is Sue Langhorst. But sometimes you can't evaluate those without your medical physicist walking you through it. And so is that -- is that a very good measurable regulatory control, or should that be more practice of medicine? That's my point.

DR. ALDERSON: Someone should comment on that, from either Mr. Zoubir or one of our two radiation oncologists.

MEMBER SUH: I mean ultimately from, you know in terms of regulation, again I think a lot is going to be on the onus of the post treatment review, as Zoubir mentioned. If the post-plan shows that you're clearly off, then ultimately it's going to be up to the health provider to say a medical event has occurred, because again, I think we've had this discussion before.

How many medical events in the U.S. are there each year, and how many are actually reported by every physician? Does every medical center out there being truly honest with every medical event that occurs? I don't know. I don't know what that numerator is and denominator is.

So again, if by this definition if we're off by -- if that 80 percent is not covered by the treatment site, then on the pulse planner unless something happened with the treatment, then it would be on me to say this is a medical event and I'm reporting it, and when the inspector and there's a deviation, we were clearly off and it constitutes a medical event.

So I think part of it's going to be communication with the inspector. So I don't -- with the definition as it currently has, can someone just flip through a bunch of charts and find this? No, that's not going to help. That's not going to happen.

MEMBER LANGHORST: But I think if you're required to have these histograms and this is one of the things you're showing, this is how this shows more than 80 percent was within 20 percent, however it showed, then you can -- that's something an inspector can look at and it shows that you've done that evaluation, and that there's assurance that what you're pre-planning circumstances were are the same as what your post-administration circumstances that you've shown you've documented, that you were within that criteria and so there was no medical event.

So I think anything you can do to push it towards something that you can really document that's easy to show the inspector, that's a good, measurable regulatory control. So I'd just encourage you to think about how the rubber meets the road, I guess, is what it comes down to. Thank you.

DR. ALDERSON: Dr. Zanzonico.

VICE CHAIR ZANZONICO: Correct me if I'm wrong Dr. Suh or Dr. Ennis, but this is a -- that criteria, an 80 percent deviating from the prescribed dose, is a pretty bad result. If you were for example flipping through dose volume histograms, that would be, I think, very obvious.

I mean I think with modern radiation

therapy, the dose volume histograms look almost perfect in terms of coverage of the tumor site, and if you were really under dosing up to 80 percent by 20 percent, I think it would be fairly obvious just visually looking at the histograms.

DR. ALDERSON: So -- we're coming wearing our hat as a regulator and we don't talk the same language. So we need to come to a middle place where we're meaning the same things. I think some of the terms and things that we use aren't completely clear, like in fact what that really means.

So I'm hearing Sue saying I need you to tell me what is a treatment site more specifically somehow, and maybe we do have to somehow put into the written directive and again, I haven't really read over recently the requirements in detail to know how it's revised. But maybe there has to be something more specific.

What is the treatment site so the regulator can say okay, I see here your documentation on this patient. This is a treatment site and now show me that, you know, the dose was delivered. The other part of this, to Pat's point and to clarify for everyone on the subcommittee. So a dose volume histogram will be based on an imaging, usually CT but it could be MRI, done in

the planning process.

Whether that was executed every day is not based right now in general on reproducing dose volume histogram based on a today imaging, but rather based on the imaging done today that is then matched to the idealized image of what it ought to look like today, and making sure that everything is lining up perfectly.

So we'll do imaging right before treatment on some basis, sometimes it's daily, sometimes it's weekly, to make sure things are lining up properly. That is the moment where we can all of the sudden recognize there's a misalignment of a significant degree, and then go ahead and say well, how much of a degree? What did 80 percent of our treatment site did not get and get the dose?

So it wouldn't be that we would have, immediately at least, a new dose volume histogram that we would comparing side by side, but it would be the imaging that was used to verify the positioning to be correct, show that it was dramatically off and therefore we determined that we had done something incorrectly.

So that's kind of the process. Now I guess we have to talk regulator language of how you translate it into regulator ease that is easy. But that's kind

of what happens, and what we're trying to get at is okay, if you're off by that much, we know what that means. But Sue wants to know how are you going to tell me what that means and I can do that independently.

Which I kind of hear but there's a gap in our language. Mike Fuller would like to comment.

MR. FULLER: Well, and again I don't want to take this down a path that's too far from where we are right now.

But I wanted to -- because it seems to me, listening to this discussion, that there is an interest in having criteria that an inspector could come in during an inspection and independently look at whatever documentation and so forth that's available, and then come to an independent conclusion about whether or not something was a medical event and whether or not it was reported.

What I would like to share and remind people of is that while there may still be some inspectors that do that, and there may be a need for someone like Dr. Langhorst, as the radiation safety officer who's doing more internal audits to be able to do something like, as an inspector we train folks over and over and over again that identifying independently medical events or independently identifying medical

events that weren't reported is not and should not be the focus of an inspection.

The focus of the inspection is to come in, through discussions and observations and interactions with the licensees, to come to a determination about whether or not the licensee has a strong, rigorous program in place that enables them, the licensee, to identify and ensure -- well first of all, I'm sorry, to ensure that any procedure that requires a written directive is done in such a way that the licensee knows when they have departed from what they had intended.

So if you start your inspection from the perspective of tell me about your program that you have written and in place and have trained your folks on, that ensures that when you write a written directive, that that actual procedure is carried out in accordance with that directive and that when it's not you know it.

If you start your inspection there, you really don't need and you make a determination that in fact this licensee has a strong program and has a program with rigor in that regard, you never really get to the point to where you need to count medical events, because once you know or once you determine as an inspector that that program does not exist or that program does not have rigor, then you don't really need

to go even at that point in time counting up how many medical events weren't reported because that's really the regulator's role.

The regulator's role is to focus more on 35.41, as it is to understanding and being able to independently identify those cases where 35.3045 happened and it wasn't reported. So anyway again, just to kind of bring people back to what the regulator's role should be. It's not counting, it's not independently counting medical events.

It is assessing the strength and the rigor that that licensee has in its program for ensuring that treatments and other procedures are carried out in accordance with the written directive. So sorry, I didn't mean to preach too much but --

MEMBER COSTELLO: Okay. This is Frank. Can I make a comment?

DR. ALDERSON: Someone's on the phone?

VOICES: Frank.

DR. ALDERSON: Frank, Frank, speak up.

MEMBER COSTELLO: Right. Can you hear me now?

DR. ALDERSON: Yes.

MEMBER COSTELLO: Okay. I'd like to comment a little bit on what Mike had to say, mostly

to agree but to go beyond it a little bit. We try to be a performance-based inspecting organization, as does the NRC and the other Agreement States, and we do begin the way Mike described. A question I'll often ask a licensee is how will they know whether or not they've had a medical event, for whatever modality we're talking about?

Then they will describe it to me and that's how I think, if we do change the definition, I would expect them to explain to me how they reviewed each individual treatment to determine whether it was a medical event or not. However, we are a performance-based organization, and it's to trust and verify.

So I might select a few individual treatment plans and look to see if the program they described to me is actually the program that they're implementing. So it's not just enough to have them tell you what they're going to be doing. At some point you have to verify using a performance-based approach, to see whether or not what they're doing, what they say they're doing is what they're really doing.

I have one other comment, kind of separate from that, and that is I notice what modalities is this new definition of medical event supposed to apply to?

So IMRTs discuss intraoperative treatment. Many of those are machine-produced. You've got to remember that we're not talking about medical events from machine-produced radiation. So if you have -- coming from the subcommittee, how much of this discussion we have applies mostly to machine-produced radiation? Thank you.

DR. ALDERSON: Comments on that?

MEMBER SUH: Well, I think this applies to the high dose rate brachytherapy. So it's, you know, if your dose is off from treatment site for more than 20 percent or 50 percent for a single event, then that would be, at least from this definition, would be considered a medical event.

Also in terms of Gamma Knife for the non-Perfexion unit, if you're off, you're not encompassing the target, that also constitutes a medical event as well. So yes Frank, some of these definitions are more related to what we think of as a linear accelerator. But again, there are some situations where I think we want to be more encompassing in terms of this definition.

So that's why we tried to make an attempt at trying to find what should constitute a medical event, and again, we came up with treatment site as

being kind of the first step and then can argue about what percent of coverage of the target would be -- the treatment site would be considered a medical event or not.

But let me just get back to one point. Again, I think just go back to some of the comments, at the, you know if -- you know again, there is a balance between regulations and delivering the best treatment, and again there's going to be a little bit of going back and forth. You want to try to make it as easy as possible for everyone involved.

But at the end of the day, if you have a high quality program, you're going to fall well within -- you're going to treat the right site. You're going to treat the right patient, you're going to treat the right location. If you look at what Ron presented earlier today, some of those medical events are reported, are you know, are -- were clearly medical events. I mean I don't think anyone would have any question about that.

So again, now we're saying okay, let's take a much more select scenario for giving as high dose radiation, and again just going back to brain and spine, which is what I do. I'm treating a T-12 vertebral body, and I'm treating just half of the vertebral body. To

me, that's a clear medical event. I've missed, and right now the definition the way it is, it doesn't really clearly specify.

So that's really what the attempt is, of saying if it's part -- well, if it's treatment site, does not cover by at least 80 percent of what I intended to treat, that would constitute a medical event. So that's --

DR. ALDERSON: Yes.

MEMBER LANGHORST: Sue Langhorst. So I wanted to come back to Dr. Zanzonico's point about oh, that would be not very good and yeah, I agree. But you can't get to perfection on a regulatory control. This is, you know, major health, public health and safety, patient safety. So you have to have -- it's not ideal from a physicist's point of view obviously, but what is that end point that really you need to report it as a regulatory issue.

So yeah, you wouldn't want to treat that way every time. But I know I did, our institution if we're outside of ten percent or five percent, that's when we're going oh, that's not how we want to treat or that's not how we want to do our diagnostic procedures. But that keeps you well. I think Dr. Suh was saying that it keeps you well within the regulatory

framework.

So yeah, you wouldn't want to do that every time, but that really tells you something went wrong there.

DR. ALDERSON: So by just listening to this, I think that the committee's done an excellent job of modernizing the criterion, and giving us some new standards. I guess the real question is, given that they're a little bit more complicated, are they understandable enough that the Committee would want to recommend that they be adopted?

I mean that seems to be the crux of what I'm hearing the discussion be. I think that among radiation oncologists, you would say the answer to that is clearly yes, and the question is, is that -- is that sufficient and that it -- in fact, it may well be. Perhaps you'd like to argue or support that point, given that these instruments are all, you know, done in using radiotherapy.

I think if that's true, then you know, there would be a feeling that we would want to support it. I think that's the only question. It's a question of can anyone else, you know, understand it and if they can't, then it's not useful at all, because no one else can understand it. Please comment.

MEMBER ENNIS: Well, my feeling is we need to have some more discussion, to figure out how we achieve that goal. So how does the regulator in particular, you know, how does this fit into the well-articulated framework that Mike laid forth about what we're really trying to accomplish, and what do we need to be saying needs to be in place for a regulator to go in and yes, verify that there are proper procedures and perhaps to independently review some cases, as Frank said, and verify all that, again without creating a tremendous amount of work for that institution, without burden, that translates this into reality.

And I think we do feel like every radiation oncologist who is worth his salt would understand what this means, does do this and would agree yes, those are medical events and this is a good step. This is reasonable. We'll see, now that it's public, what response we get from the radiation oncology community.

But yeah, I think, you know, that part is. But you know again, I think we need to kind of look a little bit broader and figure out like what do we need to make this real.

DR. ALDERSON: John.

MEMBER SUH: So I appreciate everyone's

comments. This is -- I sense this is going to be contentious. It's medical event reporting and we're spending a lot of time on the importance of safety and to protect the public, protect the patients. I see there is other stakeholders that we need to also involve as well.

So one of the things that I would ask that if it's okay, if I prepare a formal report at the next meeting, get other stakeholders, try to refine the definitions so that the regulator and the licensee would say well, this makes sense for us. Again, it may not be an easy process but we should at least try and present it again formally at the next meeting.

DR. ALDERSON: I think that's aiming in the direction that everyone's been sort of trying to go. Dr. Ennis.

MEMBER ENNIS: Do we have a regulator on our subcommittee? If not, maybe one should be added.

DR. ALDERSON: Dr. Tapp.

MEMBER LANGHORST: Yeah, Dr. Tapp.

DR. ALDERSON: Would you like to add Dr. Tapp to your subcommittee?

DR. TAPP: I cannot be added to the subcommittee, but I can be a resource at any time you contact me and I'll be a resource.

DR. ALDERSON: Yes. Would you like to be a resource?

MEMBER SUH: Yes please.

MEMBER COSTELLO: This is Frank. Actually, I'm a regulator.

(Off mic comments.)

MEMBER SUH: Yeah, Frank is a regulator.

DR. ALDERSON: So Frank, would you like --

MEMBER COSTELLO: I'd be happy if you reach out to me if you want to.

DR. ALDERSON: Frank, would you like to join this committee also? Would you like to join this committee?

MEMBER COSTELLO: Yes, I would.

DR. ALDERSON: Okay, and you're --

(Simultaneous speaking.)

DR. ALDERSON: -- a resource.

MEMBER SUH: Yes, okay. That's great.

MR. OUHIB: This is Zoubir again. If I may, this is just a comment for Frank. Wouldn't a procedure for post-implant evaluation for a possible medical event be helpful for regulators?

In other words for any modality, there is a clear procedure of how this is being evaluated to, you know, at the time of the event he says okay, what

exactly did you do? He says well here's my procedure. This is how I evaluate all cases post-implant, because they're different. We know that.

MEMBER COSTELLO: My reference regulation, Section 35.41, states that you need a procedure to make sure that the right patient gets the right dose. I would think a good procedure like that would include post-treatment analysis.

MR. OUHIB: Right, right.

MEMBER COSTELLO: So I think that a good 35.41 procedure would include evaluating the treatment to see whether or not there's a medical event or not. So I'm agreeing with you.

MR. OUHIB: Right, right, and that's exactly what we do. In other words, if we do safe procedure we have a -- or a modality, we have a certain procedure to follow, okay. Some, you might may use DVH imaging and all that, but others maybe just be imaging or what-not because you can't do a DVH on (phone interruption) or something like that.

So really, that's how we relied on. Basically it says okay, this is this type of procedure. All right, here's how we're going to evaluate it. This is good, this is good, this is questionable. Let's look further and so on and so forth. Okay. I've just

thought I'd make a comment.

DR. ALDERSON: Okay. So let's summarize, because our time is up for this discussion. We're going to add Frank Costello --

MS. HOLIDAY: Dr. Alderson. This is Sophie. I just want to remind you guys that we're limited to 50 percent of ACMUI membership to serve on the subcommittee. Currently, there are five members and you have Zoubir Ouhib as your sixth member once he becomes a full member.

So at the time, we only have 11 full members. So the subcommittee cannot have more than five members at this time. So we can't add Frank or alternatively, when Zoubir and Mr. Green join the committee, you'd have to pick between Frank or Zoubir. Sorry.

(Off mic comments.)

DR. ALDERSON: I think in this particular case, it seems like an important issue that we should continue, and we should get a report back the next time. Let me go on to the second half of this and then I'll come back to your question. I think we're going to vet the clarity of the final statements with a number of other stakeholders, and the idea would be that we'll report back in the spring, and Dr. Tapp will be a

resource to you.

So the issue is Frank Costello, who has an interest in being on and does have a vote, and Zoubir who was appointed but doesn't have a vote at this time. So I think that if you'll accept the chair's prerogative, I think Frank needs to be on the committee, someone that can vote and take an action, and Zoubir needs to be a resource to the committee. Do you accept that Zoubir?

MR. BOLLOCK: But you can only do that -- so Zoubir is actually, he was on the subcommittee. If he's not officially on the subcommittee, he's not officially --

DR. ALDERSON: Oh, he's not on the subcommittee.

MR. BOLLOCK: Officially, because he's not officially part of this committee --

DR. ALDERSON: So we don't have to invite him to step off, right.

MR. BOLLOCK: Right. So we'd still -- so officially the subcommittee has five members. So right now one member would have to step off in order to add --

DR. ALDERSON: Oh, I see. That wasn't so good. There already are five other members.

MR. BOLLOCK: Right, yeah. So that's why his name is italicized. He's not officially on the Subcommittee because he doesn't officially work for the committee.

DR. ALDERSON: All right. So please, Frank, will you be a resource to the committee also? Frank?

MEMBER COSTELLO: I'd happily be a resource.

DR. ALDERSON: Yes, very good. So we've got another resource. So you can reach out to Frank. He's not officially a member of the committee, and thus not able to do --

MR. BOLLOCK: Right, because he's -- because he is part of the Committee, you can use my staff as a resource to help and not so like Dr. Tapp is not part of the subcommittee, but she is a resource if you need to check for that, you know, for regulatory definitions and that understanding of questions. That's what you use Dr. Tapp for.

Because Frank is on the Committee, we're circumventing FACA rules if we were trying to do that. So we can't really do that. So right now, there are five official members on the subcommittee. It has to remain five. So in order to add Frank, we would have

to remove one of the five.

DR. ALDERSON: Who are the official members of the committee?

MR. BOLLOCK: Dr. Ennis, Dr. Dilsizian, Dr. Palestro, Dr. Suh and Dr. Zanzonico.

VICE CHAIR ZANZONICO: I mean I'd be happy to step off the committee.

(Laughter.)

DR. ALDERSON: Dr. Zanzonico is willing to take one for the team, all right, and resign from this committee. Thank you Dr. Zanzonico.

VICE CHAIR ZANZONICO: (off mic)

(Laughter.)

DR. ALDERSON: I didn't even ask you this time. And then Frank will step onto the committee. Frank, is that all right with you? Is that acceptable to the rules and regulations? It is. So done. So we'll look forward to a report from this group at the spring meeting. Thank you very much.

MEMBER SUH: Okay, thank you.

VICE CHAIR ZANZONICO: All right. On we go. So we're into a report from the NRC, Dr. Taylor, on 10 C.F.R. Part 35 rulemaking update.

10 C.F.R. Part 35 Rulemaking Update

MS. TAYLOR: Good afternoon. I think

you called me doctor. I'd like to clarify. I do not have my Ph.D.

DR. ALDERSON: All right.

MS. TAYLOR: I admire those that get through that program.

(Off mic comments.)

MS. TAYLOR: Okay. I am the new project manager. It seems like every time you turn around we have a new project manager, right. For this rule, my name is Torre Taylor. I'm in the rulemaking branch in MSTR. So I'm here to provide you an update on the rule. I wish I could tell you we have an SRM and official decision but we don't.

Let's see. Okay. So now on to my presentation. Well let me start, back up. I started to work on the rule in January 2016, so my work started with ACMUI recommendations and then comments from the Agreement States, and then we took it forward from there with the final recommendation just to the Commission.

So I'm going to focus on the background and the current status, highlight high level ACMUI review unless you want to get into more details and our staff response, the major changes in the final rule, which to me is the more important discussion, the final process for publication. I'll have a slide for

contacts so people can write that down with phone numbers and emails for questions, and then any questions the Committee has.

As a reminder, the proposed rule was published in the Federal Register on July 21st, 2014. I have that citation if anyone wants it. The comment period closed November 2014, and we received 69 comment letters. Some of those arrived after the end of the comment period, but we were able to consider all of them but two in the time period we were finalizing the rule.

The comments can be seen in ADAMS or in regulations.gov. For ADAMS, if you want to get some information about how to get to those specifically, I don't have a single ML number for you, but I can step you through how to find them.

I can even send you a list of the MLs, or you can go to regulations.gov and you would just go to that site and the docket ID is NRC-2008-0175. That's often for the benefit of the public. They may not be aware of the comments we received.

ACMUI did have early opportunities to review and provide comments on the draft proposed rule, and also on the final rule. The final rule was sent to the Commission via SECY 16-0080. The ADAMS number is written there, ML 16123A342. It has all the

enclosures to the rule, the Federal Register, the ACMUI report, our response, the state comments and our response and all the particulars of the rulemaking process that have to be with that.

It is public, and it's also on the website if you want to go to the SECY papers that way. The Commission is currently reviewing the rule. We do have two votes. I can't discuss those votes obviously. We're waiting on the last vote. So my discussion is based on what we sent to the Commission, and obviously the Commission may make changes.

Let's see. You all provided the report on your recommendations in January of 2016, and that's Enclosure 4 to the SECY, and then we provided a response back. That's Enclosure 5 to the SECY, and you have a public teleconference on it in let's say, when was that? It was January 6th as well.

Essentially, the high level is that you all endorsed six provisions of the final rule. There were two recommendations that the staff accepted. There was one that -- I've got that written wrong. There were two recommendations accepted. One was accepted in part and we had four recommendations that were not accepted.

The major changes is where I want to focus

the discussion. But in the reporting criteria for permanent implant brachytherapy, the proposed rule included dose base criteria for permanent implant brachytherapy. That provision has been eliminated and for within and outside the treatment site, and we now had it as source strength-based.

The medical community expressed concerns about a dose-based criteria that we're not practical, they might create confusion, they could discourage licensees from using the treatment modality, and this is a recommendation or change that the ACMUI endorsed. We did revise the language to be clear that it was based on the post-implantation portion of the written directive.

An Agreement State pointed out to us that it wasn't clear if it was pre- or post or what. So to be consistent, everything is the post-implant portion of the rule. The ME criteria for wrong location, this is in Section 35.3045(a)(2)(iii)(C). So we've revised that to state that sealed sources implanted directly into a location discontiguous from the treatment site as defined in the written directive. This was a recommendation by ACMUI.

The proposed rule would not contribute dose to the treatment site, and the Committee expressed

some concerns about that and we agreed with the Committee on that.

The other change is the reporting of failed technetium and rubidium generators. So the proposed rule and the final rule has this new requirement to report a generator eluate that exceeds permissible concentrations of their respective radionuclides.

After reviewing the public comments on the proposed rule, we changed the notification and reporting deadlines. So the notification deadline is going to be within seven calendar days. The proposed rule had that as 30, and the deadline for submitting a written report is within 30 calendar days, and the proposed rule had that as 45.

We deleted the separate category for training experience for alpha emitting radiopharmaceuticals for parenteral administration. So that's all been included in 35.390(b)(1)(ii)(G)(3). So that provision is now everything related to electron emission, beta radiation characteristics, alpha radiation characteristics or photon energy of less than 150 keV for which a written directive is required. So there's no longer a separate category there if obviously the Commission approves that.

A big issue in the proposed rule stage and

comments was the compatibility category for medical events for 35.3045. After reviewing all the public comments and the comments from the ACMUI and the Agreement States, the staff's recommending to the Commission that this be designated as a Category C.

The essential objections have to be met by the Agreement States to avoid conflicts, duplications or gaps in the regulation. It doesn't have to be exactly the same as NRC requirements, but they have to meet the essential objectives. They can require reporting of MEs with more restrictive criteria than those required by the NRC, but we did make clear that we do not consider a dose-based criteria as part of the essential objective for this section of the regulations.

The main reason for essential objectives is we want a consistent national program. We determined that the dose-based criteria could conflict with and create inconsistencies with a national program, and we could end up with reports of non-significant events.

It allows the NRC to identify trends or patterns, identify generic issues, recognize the inadequacies or unreliability of certain equipment or procedures and why an event occurred, and whether any

actions are necessary. So that's where that fell out and we'll see if the Commission agrees, because if you remember, they came back and told us to notice it as a B and then asked for comments, and we got a lot of comments.

Okay. The final process. It's with the Commission. We're waiting for a staff requirements memorandum. At that point, once we get that direction we'll make any changes that they direct and then we will send the package over to the Office of Management and Budget for their review and approval. That can be a 90 day process. Hopefully it will be shorter rather than longer, but we don't know.

If we get an SRM in October, I'm estimating the earliest we could publish this rule would be in the spring of 2017. The rule will be effective 180 days from its publication date. So that's six months, and then the Agreement States will have three years from the effective date to adopt the provisions.

Now often it's the publication date; in this rule we're doing the effective date. The medical team is going to finalize guidance for this rule, and they will be the one to address any questions anyone has on that along the way.

Here are the contacts. I am the person for

the rulemaking process, Torre Taylor for those on the -- well I guess everyone signed up for GotoMeeting, right? So there's my email and phone number, and then Mike Fuller and Doug Bollock can address any specific technical questions, and I think that's all I have, except for any questions y'all have.

DR. ALDERSON: All right. Questions for Ms. Taylor.

VICE CHAIR ZANZONICO: I have a question. I was always under the impression that the Commission was sort of the omnipotent adjudicator of all the rules and regulations and so forth. But I see it goes back -- it goes to OMB after Commission approval?

MS. TAYLOR: Well, the Commission approves it for the agency. OMB is a government-wide review. They make the final, final say. They won't change anything technical, but they look at resources, budget from a government perspective and say is this a major rule, is it not a major rule and they make that kind of determination.

So if they reject it, we wouldn't be able -- we wouldn't be able to publish it.

VICE CHAIR ZANZONICO: Well that's the question. I mean --

MS. TAYLOR: I don't think that would

happen.

VICE CHAIR ZANZONICO: Is the OMB review ever involve sort of in the sense restarting the process?

MS. TAYLOR: I don't think so.

VICE CHAIR ZANZONICO: In other words, can they find schematic issues with it that --

MS. TAYLOR: No.

VICE CHAIR ZANZONICO: Not that to have to start from scratch, but there were major issues to revisit and --

MS. TAYLOR: No, not from a technical perspective, yes.

DR. ALDERSON: Other questions? Yes.

MS. HOUSEMAN: Torre, please -- is this on? Please -- oh, this is Esther Houseman, OGC and NRC. Torre, please correct me if I'm wrong on this, but the OMB review, because we're an independent agency and don't have to send rules through OIRA, the OMB review is just for Congressional Review Act purposes; correct? Because it is a major rule.

MS. TAYLOR: Yeah. Actually yeah, so --

MS. HOUSEMAN: And that's for OMB to review the rule and determine whether it needs to go to Congress under the Congressional Review Act?

MS. TAYLOR: Oh okay.

MS. HOUSEMAN: The Congress almost never takes up rules for Congressional review.

MS. TAYLOR: Oh okay, that's good to know.

MS. HOUSEMAN: Just so you're aware. It's for a very narrow purpose that OMB looks at the rule.

MS. TAYLOR: Okay, thank you.

DR. ALDERSON: Other questions?

(No response.)

DR. ALDERSON: So there are none.

MS. TAYLOR: Okay, great. Thank you.

DR. ALDERSON: Thank you for your report.

MS. TAYLOR: We should have a final rule.

DR. ALDERSON: So now we're going to -- Mike Fuller is going to speak with us on NRC comments on patient intervention.

(Pause.)

NRC Comments on Patient Intervention

MR. FULLER: Thank you Dr. Alderson. Yes, I'm Mike Fuller, the team leader of the Medical Radiation Safety Team here at the NRC. I appreciate the opportunity to speak to everyone today about patient intervention, and the title of my presentation

should give you a hint.

So it's entitled, the document I want to talk about, because it's patient intervention and how do we proceed. So the purpose of my presentation today is to review the ACMUI recommendations related to the definition for patient intervention, and discuss the challenges that are facing NRC staff as a result of those.

First, to give you just a little bit of background and I guess short history, it wasn't that long ago, back in March of 2015, Dr. Gabriel, who we heard from this morning from Vienna, who at that time was a member of the Medical Radiation Safety Team here and Mr. Frank Costello of the ACMUI, made a couple of presentations to the ACMUI.

Sandy's presentation was really focused sort of on the background and the history of the term patient intervention, and how the NRC came up with the definition and when and so forth and so on. And then Frank provided a presentation that was a little bit more focused on apparent misalignment between the meaning of patient intervention between the NRC staff and the ACMUI, or at least according to Mr. Costello.

So as a result of that, of those two presentations, the chairman at that time formed a

subcommittee and charged that subcommittee with clarifying the meaning of patient intervention, to make sure that the Nuclear Regulatory Commission and the advisory committee or the ACMUI are aligned in their interpretation of the term patient intervention.

So then last fall, in October of 2015, we heard a presentation by Dr. Dilsizian of the ACMUI. He presented the subcommittee. So that subcommittee was formed. Dr. Dilsizian I believe chaired that subcommittee, and he presented the subcommittee's recommendations to the full committee.

So with some changes to those recommendations, the full ACMUI provided staff with the following recommendations, and these recommendations are really on two separate issues. So Issue 1 in the first recommendation states that "an intentional/unintentional patient action would represent a reportable medical event, even if it results or will result in" -- I'm sorry, "a reportable medical event if it results or will result in unintended permanent functional damage to an organ or physiological system as determined by a physician."

And of course the overall goal would be to prevent or mitigate patient action that may impact treatment. In reviewing the presentation from Dr.

Dilsizian and looking at what the current rule says, we've taken this to mean that, with maybe some minor modification in the wording although it's not clear, that they were endorsing what we currently have.

The second issue and the second recommendation I think is really where we need to focus, and that's where I'm focusing my talk today. The second issue had to do with anatomic and physiological anomalies, and the recommendations that the staff captured from that presentation is provided here.

So unintentional treatment outcome due to anatomic or physiological anomaly and/or imaging uncertainty falls into the category the art of medical practice, provided that the standards of medical practice are met. Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future and therefore cannot be regulated.

So at this point, NRC staff or we on the medical team are assuming that the ACMUI wishes the staff to state or conclude that the current definition encompasses this new criteria. So here's what the regulations currently say, or this is how the regulations currently define patient intervention.

Patient intervention means actions by the

patient or human research subject, whether intentional or unintentional, such as dislodging or removing treatment devices or prematurely terminating the administration.

So before I get into the discussion or my part of the presentation about possibly making changes, I want to explore further a little bit about what, just what problem it is that we're trying to solve. I say that because in Mr. Costello's presentation in March of 2015, the primary concern was focused on yttrium-90 microspheres.

So I've taken these two quotes directly from Mr. Costello's slides, where he states and I think he's -- well, based upon the presentation, it's clear that he's speculating or assuming. So he said the patient's artery contracts and the spheres flow retrograde into the gastrointestinal artery. In another place he says if the patient's lung shunt fraction was one value during the workup and changed for the treatment.

So I want to remind folks that this past February, in fact on February 12th, the NRC issued Rev 9 or Revision 9 to the yttrium-90 microsphere brachytherapy sources and devices, TheraSphere and SIR-Sphere licensing guidance. In that revision, we

made changes such that there's an exemption made for shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures.

Back in June of 2012, the NRC issued Rev 8, and in that revision there was an exception made for emergent patient conditions that prevent administration in accordance with the written directive, and we actually stated and used specific examples that related to artery spasm or sudden change in blood pressure.

So that's why I say I want to explore a little bit more at this point in time about what is the problem that we're trying to solve. So if you'll recall back to the then-chairman, ACMUI chairman's charge, it was to evaluate or to take a look at the definition of patient intervention and two, and let me read it again.

So to clarify the meaning of patient intervention, to make sure that the Nuclear Regulatory Commission and the ACMUI are aligned in their interpretation of this term. I can say today that it's clear that we're not aligned, and that the NRC staff cannot implement the ACMUI recommendations as currently written.

So the first recommendation, what we called Issue 1, it's not clear what the difference is. I mean we could go back and look at that and evaluate that more closely. But reading the words that were presented and reading the words that are currently in the rule, it's not clear what the real difference is.

But for Issue 2, at this point in time it's not implementable, and so other than yttrium-90 microspheres, which I think we have addressed, I'm not certain what the concerns are. Perhaps some of you are aware of instances where maybe a licensee determined that a situation was not a reportable medical event due to patient intervention, and then the regulator, say an inspector or someone, disagreed and determined that the circumstances surrounding a certain case did not constitute patient intervention.

I'm not aware of any such instances or cases, and so -- but it is possible that that has occurred. So and here's the other part that I think is the real crux of the situation. Based upon my evaluation of the recommendations that we received and where we are with the current regulations, I believe that this really is more of a legal issue rather than a technical one.

So according to 10 C.F.R. 1.23, the NRC's

Office of General Counsel provides interpretations of laws, regulations and other sources of authority, and patient intervention is defined in 10 C.F.R. 35.2. Now the -- I think there are a couple of different ways we might could proceed.

If the ACMUI wishes, we could go to our Office of General Counsel and ask them if the additional language that was recommended, and that really has to do with Issue 2, the unintentional treatment outcome due to an anatomic or physiological anomaly and/or imaging uncertainty falls into the category of the art of the practice of medicine, provided that the standards of medical practice are met.

Again, I'm not an attorney, but I read the definition, the current definition of patient intervention and I don't see how we can get there. But if the ACMUI would like for us to, we could go to our Office of General Counsel and ask them if in fact that definition could be interpreted such. But in order for us to do that, frankly we're going to need a little bit more from the ACMUI.

We're going to need some -- I mean I can't, I can't assume and take the slides that we received with those recommendations, and then try to fill in the blanks and assume what the basis is for that. So at

a minimum, I think if the ACMUI wants to proceed to do that and go to OGC for an interpretation, we would need a report, I believe, that fully fleshes out these issues and provides us with the basis for these -- for these recommendations.

And the other thing that of course we could do, but it would require some of the same sort of efforts on the part of the subcommittee, is we could go to rulemaking. That's always an option. But we all know what that entails. In other words, you would have to -- we would have to develop a rulemaking plan. We would have to get the Commission to agree to go forward with rulemaking, and then we would do the public, the full-blown multi-year process of changing the regulations to change this definition.

So that's kind of where we are, and I would welcome your comments and your thoughts on this.

DR. ALDERSON: Yes. Laura Weil.

MEMBER COSTELLO: This is Frank. Can I make a comment?

DR. ALDERSON: Okay. Just Laura's going to speak first, Frank, and then you'll come.

MEMBER COSTELLO: Okay.

MEMBER WEIL: If I'm hearing you correctly, and correct me if I'm wrong, you're saying

that the current 10 C.F.R. Part 35 definition, as outlined on Slide No. 6, is adequate?

MR. FULLER: Well, what I'm saying is that that is the current definition. That is in our regulations and that is -- and if we wanted, if the ACMUI wanted us to state or communicate out that it encompasses the recommendation that we talked about in Issue 2, staff does not have the authority to do that.

We would have to go to our Office of General Counsel and get them to agree that that -- and specifically what I'm talking about is that anatomic or physiologic anomalies and/or imaging uncertainty thought would need to be incorporated or they would have to agree that that's already there, that that could be -- that this definition could be interpreted to encompass those things, because the staff doesn't have the authority to do that interpretation.

And what I've said further was in order for us to go to OGC, we're going to need some help, because looking at the presentation, we don't see -- in other words, I wouldn't want to try to assume what the basis was without getting it from the ACMUI. We would have to -- this would be a formal process that we would have to go through, that we would have to develop the documents and send them to OGC for them to evaluate and

get back to us.

DR. ALDERSON: Okay Frank, you're next.

MEMBER COSTELLO: Okay. Basically, I raise this issue because in my experience with the NRC I was very familiar with this definition, how we interpreted it in the past, and in discussions on a number of issues, it became clear to me that patient anomalies were being thought of as being patient intervention. If the patient's physical anomalies result in a dose not being delivered as intended, that was being thought of by any number of people as being a patient intervention.

I used microspheres as an example because we hadn't changed the definition of a medical event yet. That comes from the six months or whatever it was. However, I think -- as I think about it, there might be other situations and other modalities where patient anomalies may result in the dose, through no fault of the medical treatment staff, not being delivered just because of the way the patient was built.

However, at the time I came up with those because that was on my mind. There may be others, and maybe someone else can think of some. Thank you.

DR. ALDERSON: Yes, Sue.

MEMBER LANGHORST: Again, I apologize. I

wasn't here last year to talk about this during that presentation. But there is -- I'll give you an example, Mike. I brought -- I had one ready for that meeting and couldn't do it. So in 1980, the NRC had the final rule for misadministration, and in there, they said, in the final rule documentation, extravasation is the infiltration of injected fluid into the tissue surrounding a vein or artery.

Extravasation frequently occurs in otherwise normal intravenous or intra-arterial injections. It is virtually impossible to avoid. Therefore, the Commission does not consider extravasation to be a misadministration. The NRC asked ACMUI to review this again in, oh gosh when was that, that was 2009, and there was a teleconference on the diagnostic point of that and also then they asked could you talk about this in regard to therapeutic administrations.

And so that was presented in the spring meeting of the ACMUI, and at that point in time the NRC stated that it was determined that extravasation does not require reporting as a medical event. They asked the ACMUI on the therapy part and ACMUI said yes, you should continue to have that policy.

I'm not sure it was clear that the NRC staff

accepted that, but there's been no other change in policy in that regard. So that's kind of buried in historical information that isn't necessarily clear, that it's never related to patient intervention.

And so patient intervention having that definition and knowing what it means has a big impact on licensees because of medical event reporting and if you say it's patient intervention then you have that Item B on permanent impact to a tissue or organ. So that's the problem we're trying to solve, to make sure we're all talking the same thing.

MR. FULLER: Right, and so -- and I think it might mean -- and I'm sorry. I don't have what you have in front of you, right in front of you. But I would appreciate if you'd read that again, because when I heard you talk about extravasation, it's not -- nowhere in there do we say that that is patient intervention.

MEMBER LANGHORST: Right.

MR. FULLER: So that's the point I'm trying to make, and that is what we were asked -- the recommendation, or what we took from the presentation was it looked like we were being asked to declare or state that anatomic or physiologic anomalies are considered, and again I'm having to fill in the blanks and make assumptions, but they all would be considered

maybe involuntary actions.

That's the part I'm trying to get to, and we just can't do that right now. Yeah, unintentional. So when we -- when I read, and we have it up here, "patient intervention means actions by the patient or human research subject, whether intentional or unintentional, such as," and then we give the examples. "Dislodging or removing devices, or prematurely terminating the administration."

So I'm not arguing the merits of this, of these recommendations. I'm just simply pointing out that we have a process that we have to follow, that only certain folks can interpret our regulations. If we want to change the regulations, we have a way to do that and so forth and so on. That's the purpose of my presentation. It's not that we're taking a stance one way or the other on the merits of the argument.

DR. ALDERSON: So the question that I heard articulated is, and I know we discussed anatomic anomalies in some depth, that you're saying is do we believe that anatomic anomalies are captured within that statement, and I think the answer is no, they are not. So that if anatomic anomalies are going to be part of this, and I believe the Committee feels that they

should be based on previous discussions, then you need to have some rewording done.

MEMBER LANGHORST: No, no.

DR. ALDERSON: Let me finish. You need to have -- I think you need to have some rewording done. I don't think it's a legal issue. I think it's a medical issue at this point. Now Sue.

MEMBER LANGHORST: Sorry. I say no because you don't want it necessarily in patient intervention, because that drags it into the medical event arena. It's where you put that or where that's considered, and it, you know, again it comes to that definition of what's practice of medicine versus what can be regulated.

DR. ALDERSON: Right, okay. Dr. Dilsizian.

MEMBER DILSIZIAN: So we did struggle with this and I think again, just to summarize quickly, the dislodging of device was an easy one. Patient accidently or unintentionally, you know, the device comes out and that's why Rule 1 wasn't changed really. I really do. So we agreed with that.

MR. FULLER: Okay.

MEMBER DILSIZIAN: The discussion was about physiological or anatomical anomalies. In

essence, the patient didn't do anything wrong or take the Y-90 example.

MR. FULLER: Uh-huh.

MEMBER DILSIZIAN: You're trying to treat the liver, the gastric artery's adjacent even though they may coin it or not. Then maybe some Y-90 goes backwards and now you have a stomach ulcer, which is what Frank was seeing in his regulatory stage, as he was reviewing these cases.

So he brought up the case well, what are we doing? We have these patients having ulcers. Well, how can we prevent it? Well, this is where the discussion started. So even with your best efforts sometimes, you're going to have some reflux. Now there may be permanent damage or temporary long ulceration. Is that something that is reportable or not, and the question ultimately we said these things happen. It's anomalous or physiological that regulators cannot really regulate that, and therefore the conclusion was not to be regulated.

So I agree with you. It doesn't fit into this definition, but the question is does it belong anywhere and we should be talking about this.

MR. FULLER: And that's why I asked the question the way I did, because if you look at the time

line of, you know, when this information was brought to us, we had a separate recommendation from the ACMUI to change the yttrium-90 microspheres licensing guidance. In that, because it's 35.1000, we can define what is a medical event or what needs to be reported as a medical event.

So we made those changes. In those types of situations that Frank described and the ones that you just described are repeated are no longer required to be reported, assuming that folks did the diagnostic studies appropriately prior to the administration. We had already previous to that, and I thank Frank for his clarification.

Again, where the arterial spasm is something that we recognize should not have to be reported as a medical event. It's far beyond the control of the licensee. So we changed that licensing guidance and made it clear to the community that those are not medical events. We didn't change the definition of patient intervention to get there, and that's the point of this presentation today.

And so that's why I kind of asked, okay, do we still have other instances that we can think of, where the general definition in Part 35 needs to be changed, such that -- and of course we don't know what

the future holds always. But my point, the whole point of this presentation is to let folks know that, you know, we're not taking a stance one way or the other about whether or not the definition ought to be changed.

That's why it's more of a legal question rather than a technical question, and again I think you and I are saying the same thing, Dr. Alderson, maybe just coming at it from a different perspective. If in fact the ACMUI wants us to say that anatomic or physiologic anomalies is captured in this definition, that's where I say the legal -- that's where the legal question comes in because again, I don't think any of us believe that.

But if that's the stance of the ACMUI, then the lawyers or our Office of General Counsel would have to do that evaluation and analysis and get back to us I think. Anyway, so I'm repeating myself now.

DR. ALDERSON: Yes. So I think my sense is the medical community is, you know, I believe that normal variations in human biology, physiology and its interaction with the world can't be, should not -- lead to a medical event. I hear you saying that essentially in the practical sphere, we've kind of dealt with it right now through rulemaking, because it's in the 1000 category, which I think is actually true. I don't feel

like there's another issue pushing.

But it would seem likely that some other intervention, some new modality will come down the road, and we'll be back to square one with it again, and it might not -- I think it would be wise if it was practical to get it dealt with now. I guess what you're saying is the only real way to do that, there are only two ways to do that.

One, ask the lawyers can they read into unintentional in the way we would like it to be, that definition expanded to mean not just unintentional mechanical category but unintentional like I didn't know I was made that way; I didn't mean to be made that way, that made a shunt, right? That would be what we were talking about.

And I mean if it's not incredibly burdensome, I think asking the lawyers to try to make that interpretation would be valuable going forward so that issue would be settled. If that's not doable and you say it's rulemaking, and I think we would all probably agree it is not such a pressing issue in a practical sense to go through rulemaking.

DR. ALDERSON: Yes, we had a comment. Microphone.

MS. COCKERHAM: This is Ashley Cockerham

with Sirtex Medical. Just a comment for -- while I appreciate that it was added to the guidance to allow for these anatomic variations, not all of the Agreement States implement the guidance as written, nor are they required to because Part 35.1000 is Compatibility D.

So if something like this was to be added to the definition in Part 35 as 35.2, the Agreement States would be more consistent with I think what the Committee is intending here.

DR. ALDERSON: Yes Laura.

MEMBER WEIL: Looking at your definition, the existing definition, we were discussing at some meeting, I don't remember which one, patients who have radioactive seed implantation for breast cancer localization, don't return for removal. That's patient intervention, but it's not caught in that definition.

I don't know that it rises to the level of medical event, but it's definitely not caught in there.

MR. FULLER: Well, I would argue that if someone fails to return, that that is an action.

MEMBER WEIL: It's an action, yes.

MR. FULLER: And that that action was intentional, and that it resulted in prematurely terminating the administration.

MEMBER WEIL: I don't see prematurely terminating the administration.

MR. FULLER: Maybe not prematurely terminating, but prolonging. In other words --

MEMBER WEIL: It's interfering with the plan.

MR. FULLER: Yeah. Well, here's again. If that question, if that question came to us and we've dealt with that in a different way obviously --

MEMBER WEIL: Yeah, several times, yeah.

MR. FULLER: Because we could, because it's 35.1000. But if that question came to us --

MEMBER WEIL: Oh, it's 1000, okay.

MR. FULLER: --then we would have to -- we would have to ask for an interpretation. We would have to -- we would do what's called a technical assistance request and we would say this is what the staff's position is. We believe that this is correct, and then we would ask the attorneys to tell us if we were correct or not.

DR. ALDERSON: Dr. Langhorst is next.

MEMBER LANGHORST: I would just propose the thought that these types of things may not be appropriate to put in patient intervention, but that there be some other term defined that covers these types

of things, so that licensees and regulators understand this is -- this cannot contribute to a medical event, such as the extravasation, that you don't have to go to your law library to look up all the details on it to get to it.

DR. ALDERSON: Mr. Green, you had the next comment.

MR. GREEN: Looking at the existing definition, if the last word "administration" was to change to "procedure," would that encompass the patient's localization brachytherapy seed, breast cancer?

MS. HOLIDAY: Dr. Alderson, if I can just clarify. Ms. Weil made a comment about the radioactive seed localization guidance and the fact that we called out patients who do not return for their ex-plantation surgery. That's not captured in the medical event reporting portion of that guidance as patient intervention.

What that section actually says is that for whatever we say it's a medical event, except for those that result from the intervention of a patient or human research subject, or a patient not returning for their scheduled surgery or the physician determination. I just wanted to clarify that.

DR. ALDERSON: Yes, Mr. Fuller.

MR. FULLER: I noticed that our legal counsel, Esther Houseman, has moved to the microphone a while back, and I've probably taken all sorts of liberties. I would just like for you to recognize. I know she had some comments.

DR. ALDERSON: Certainly. Ms. Houseman.

MS. HOUSEMAN: Yes. I wanted to add just clarification on the service that OGC would provide to help resolve this issue. So first of all, and I'm not incredibly familiar with this particular provision of 10 C.F.R. 1.23, but I believe that the paragraph you're referring is typically -- what they're referring to is a public interpretation of law, policy, etcetera.

OGC rarely uses that tool. So often if we provide a legal interpretation, it is -- it is advice that OGC provides to its client, the NRC staff. So you won't necessarily see a legal memo authored by me or someone else in OGC. But we do provide assistance on that front. It's just often not public, and I do want to make sure that you understand that.

The other thing I want to clarify is OGC's role in helping to resolve an issue like this. What I can assist in doing is helping the staff and taking ACMUI's recommendations into consideration, and

looking at this definition and figuring out is the ACMUI's recommended reinterpretation a reasonable interpretation of the definition that's in 10 C.F.R. right now.

If it's not a reasonable interpretation, then the difficulty that you run into is that the agency could unreasonably interpret some regulations, and that would come with litigative risk, and OGC would advise the staff on that.

In terms of what the definition should be, that's very much more of a technical question than a legal question. So just so you know on what the definition should be and as Dr. Langhorst mentioned, you know, whether there should be a separate definition and separate term entirely is more of a technical question for you all to discuss, and how to go about revising 10 C.F.R. or reinterpreting the meaning of this definition of patient intervention is something that OGC can assist with.

DR. ALDERSON: Okay, thank you. I'd like to -- that's a very good comment, thank you. What we appear to be trying to do here, I don't think we can accomplish it. That's in Part 35 definition, and what I hear you all doing, well-intentioned, is trying to wordsmith that definition. Let's add a word here,

let's take a word out there.

That isn't going to go anywhere. Certainly not today and not anywhere when you consider what rulemaking is. So I believe that if we think that this is not an adequate inclusion of all the various things we've talked about, and that that needs to be out there in a more permanent way or a better way than 35.1000, then we probably should put a subcommittee together to start working on that, and then create some advice that's more inclusive than this is.

But I don't think that sitting here today, you know, we can take it much further by the sort of discussion we're having right now. If someone disagrees with that point, then speak up. You disagree with that point?

MEMBER LANGHORST: No. I just --

DR. ALDERSON: No?

MEMBER LANGHORST: --suggest that maybe the subcommittee that worked on the original thing could take it up.

DR. ALDERSON: That would be fine. That would be fine. If that subcommittee would be willing to continue to work on this issue, that would be fine. But right now we're at a point where they can't work with what's up there and what we think. So we've got

to resolve that dilemma. So I will -- Sophie, do you know right now who was on that subcommittee?

It should take two minutes. I would suggest that we do that after we take a break. We're ten minutes into the break period, and perhaps Sophie you can come and tell us that when we reconvene at three o'clock.

MS. HOLIDAY: I can tell you who the subcommittee members are.

DR. ALDERSON: Oh now you can do it. You are very fast.

MR. FULLER: And we need to do it before we go to closed session.

MS. HOLIDAY: The previous subcommittee members, and I'm going to exclude you Dr. Alderson.

DR. ALDERSON: Yes, have to exclude me, right.

MS. HOLIDAY: Include Mr. Frank Costello, Dr. Dilsizian as the chair, Dr. Ennis, Dr. Suh and Ms. Laura Weil.

DR. ALDERSON: So is that group of five people, are you all willing to take this up further? Yes. Very good.

MEMBER COSTELLO: Sure.

DR. ALDERSON: Then excellent, good.

Well then that subcommittee will take up this issue, and then report back to us at the spring meeting, yes.

MR. FULLER: And can I ask just one housekeeping question, and perhaps Sophie or Michelle can help me with this? So we've had a recommendation. I think it's clear we are unable to implement and follow that recommendation fully. So with this presentation and this new charge to the subcommittee, will we be able to close out that recommendation, that has been sitting out there now -- or actually there's two recommendations that were presented to us last fall. Can we close those?

MS. HOLIDAY: We cannot close them until the Patient Intervention Subcommittee presents and the ACMUI votes on the action at the next meeting.

MR. FULLER: Okay.

DR. ALDERSON: Good. Thank you. Vasken.

MEMBER DILSIZIAN: Could we have a staff member to at least direct us what all we can --

(Simultaneous speaking.)

MEMBER DILSIZIAN: We know what we want to say.

MS. HOLIDAY: Your previously appointed --

MEMBER DILSIZIAN: But the question is how we resource.

MS. HOLIDAY: I'm sorry. Your previously appointed resource staff person is Ms. Maryann Abogunde.

MS. ABOGUNDE: Over here.

DR. ALDERSON: Okay, very good. So you have a staff person.

MEMBER DILSIZIAN: Okay, good.

DR. ALDERSON: Good, thank you. I think at this point let's call this discussion to a close, and we'll now take a shorter break and we will reconvene at three o'clock.

(Whereupon, the above-entitled matter went off the record at 2:40 p.m.)