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UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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MEETING

+ + + + +

WEDNESDAY,

MARCH 7, 2018

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The meeting was convened in room T2B3 of Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, at 8:30 a.m., Philip Alderson, Chairman, presiding.

MEMBERS PRESENT:

PHILIP O. ALDERSON, M.D., Chairman

VASKEN DILSIZIAN, M.D., Nuclear Cardiologist

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

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

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

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

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

LAURA M. WEIL, Patients' Rights Advocate

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

NON-VOTING MEMBERS PRESENT:

RICHARD GREEN

ZOUBIR OUHIB

MEGAN SHOBER

NRC STAFF PRESENT:

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

DOUGLAS BOLLOCK, ACMUI Designated Federal Officer

SOPHIE HOLIDAY, ACMUI Alternate Designated Official and ACMUI Coordinator

MARYANN AYOADE, NMSS/MSTR/MSEB

JENNIFER BISHOP, R-III/DNMS

RUSSELL CHAZELL, SECY/RAS

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

LISA DIMMICK, OEDO

SARA FORSTER, R-III/DNMS

ROBERT GALLAGHAR, R-I/DNMS

MICHELLE HAMMOND, R-IV/DNMS

LATISHCA HANSON, R-IV/DNMS

PATRICIA HOLAHAN, Ph.D., NMSS/DRM

VINCENT HOLAHAN, Ph.D., NMSS/MSST

ESTHER HOUSEMAN, OGC/GCLR/RMR

NRC STAFF PRESENT (CONT.):

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

MEMBERS OF THE PUBLIC PRESENT:

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

MEMBERS OF THE PUBLIC PRESENT (Cont.):

A. ROBERT SCHLEIPMAN, Partners Healthcare

CINDY TOMLINSON, ASTRO

TABLE OF CONTENTS

P R O C E E D I N G S

8:40 a.m.

CHAIRMAN ALDERSON: Welcome to this meeting of the Advisory Committee on Medical Uses of Isotopes. And to get the meeting agenda started, I'll turn the program over to Mr. Bollock.

MR. BOLLOCK: All right. Thank you, Dr. Alderson. Good morning, everyone. As the Designated Federal Officer for this meeting, I'm pleased to welcome you to this public 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 Event Assessment Branch, and I have been designated as the federal officer for this advisory committee in accordance with 10 CFR Part 7.11.

Present today is the alternate Designated Federal Officer, Ms. Sophie Holiday, our ACMUI coordinator. This is an announced meeting of the Committee. It's 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 may also be transcribed where recorded

by others. The meeting was announced in the February 7th, 2018 edition of the Federal Register, Volume 83, page 5465.

The function of the Committee is to advise the staff on issues and questions that arise in the medical use of byproduct material. The Committee provides counsel to the staff but does not determine or direct the actual decisions of the staff or the Commission. The NRC solicits the views of the Committee and values their opinions.

I request that, whenever possible, we try to reach a consensus on the various issues we will discuss today, but I also recognize there may be minority or dissenting opinions. If you have such opinions, please allow them to be read into the record.

At this point, I'd like to perform roll call on members participating today. Dr. Philip Alderson.

CHAIRMAN ALDERSON: Here.

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

VICE CHAIRMAN ZANZONICO: Here.

MR. BOLLOCK: Thank you. Dr. Vasken Dilsizian?

MEMBER DILSIZIAN: Here.

MR. BOLLOCK: Thank you. Dr. Ronald Ennis? Okay. I did see him, and it looks like he stepped away for a moment. 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. Mr. Michael Sheetz? Dr. John Suh?

MEMBER SUH: Here.

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

MEMBER WEIL: Here.

MR. BOLLOCK: Thank you. So we do have a -- I confirm we do have a quorum of at least six members. At the table, we also have Mr. Zoubir Ouhib.

MR. OUHIB: Here.

MR. BOLLOCK: Mr. Richard Green?

MR. GREEN: Here.

MR. BOLLOCK: And Ms. Megan Shober?

MS. SHOBER: Here.

MR. BOLLOCK: Mr. Green has been selected as the ACMUI nuclear pharmacist. Mr. Ouhib has been selected as the ACMUI therapy medical physicist, and Ms. Shober has been selected as the ACMUI agreement state representative. Mr. Ouhib, Mr. Green, and Ms. Shober are pending security clearances but may participate in the meeting. However, they do not have voting rights at this time.

I would also like to add that this meeting is being webcast, so other individuals may be watching online. We have a bridgeline available, and the phone number is 888-790-6447. The passcode to access the bridgeline is 79006 followed by the pound key.

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 also closed captioned. I would also like to add that handouts and agendas for this meeting are available at the NRC's public Web site.

At this time, I'd ask that everyone 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 Ms. Linda Howell, Acting Deputy Director of the Division of Material Safety, Security, and State and Travel Programs, for some opening remarks.

MS. HOWELL: Thank you, Doug. And good morning, Committee members. As Doug noted, I'm the Acting Deputy Division Director for a newly-named division. It's Material Safety, Security, and State and Travel Programs Division. In accordance with a project that the agency initiated a couple of years ago, we have removed rulemaking from our division activities, so we decided to re-name ourselves.

First off, I'd like to thank all of the Committee members not only for your attendance today but your hard work and contributions over the past year and several years prior to that. We do truly value your contributions, your knowledge, and your expertise, and the agency does need your input in order to maintain an effective regulatory oversight program.

Just so that you know, a few changes in the last couple of months that may continue. Dan Collins, whom most of you know as the division director, is currently on rotation to Region I as the Acting Deputy Regional Administrator. Kevin Williams, his deputy whom I think you met at the last meeting, is currently the Acting Division Director, and then I've joined Kevin as part of the management team for the division. And that will extend over the next couple of months.

As I noted, we just recently changed the name, so you will see in our correspondence and communications with you, instead of MSTR, MSST. Okay?

I'd also like to note a couple of changes within ACMUI not only for the Committee members but for the attendees here in the audience.

This is Dr. Zanzonico's last meeting, as his term on the ACMUI ends tomorrow. We are sorry to see your departure, but we want to thank you for your many contributions over the past eight years and we anticipate making a selection for Dr. Zanzonico's backfill shortly.

With your departure, we do anticipate that Mark Dapas, the office director, will be providing a tribute to Dr. Zanzonico tomorrow in advance of the Commission meeting. So we look forward to that.

As Doug noted, we have a new member here at the table with Megan joining us. Thank you very much for joining us as the Agreement State Representative. We also need to note Dr. Alderson, as the Chairman and Health Care Administrator, is up for a second term on March 23rd, and you've informed us that you do not plan to serve that full second term, but will stay on board until your replacement obtains his security clearance. And Dr. Robert Schleipman has been selected as the next Health Care Administrator representative. I think he may be on with us this morning as webcast, but I haven't had a chance to talk with him this morning. So we look forward to him joining the Committee, as

well.

We do have to appoint a new Chairman and Vice Chairman with the departure of two of our senior members of the Committee. And it gives me pleasure to inform you that we have appointed Dr. Chris Palestro as the new ACMUI Chairman and Dr. Darlene Metter as the Vice Chairman. Their appointments will become effective on March 9th, so we congratulate both of you in your new positions and look forward to your leadership on the Committee.

Dr. John Suh, our representative in gamma stereotactic radiosurgery radiation oncology, will complete his second and final term here shortly. We've already issued a call for nominations in the Federal Register, and those nominations were due to be sent to Ms. Holiday by April 3rd, 2018. So we look forward to keeping you all informed on that process, and thank you very much, sir, for your service. We do appreciate it.

Going on to a few other recent activities at the Commission level, several things have occurred since the last meeting, which was fall of 2017, including issuance of a SECY paper and the staff's evaluation of our program

regulating patient release following radioisotope therapy. That paper was signed out at the end of January this year.

The paper conveyed the staff's efforts as they relate to evaluating whether significant changes were warranted regarding our regulations for patient release, and those are found under Title 10, CFR 35.75. We determined that changes to the rule text were not necessary, although we will be forwarding some updated guidance to the staff on that. But we do not anticipate making any further rule changes at this time.

We do appreciate all of your insights and input on that. It was a significant effort over a prolonged period of time, and your insights were very valuable to helping us arrive at a sound conclusion on that.

Also, as most of you are aware, the Commission has approved some final rule changes on the medical use of byproduct material that went out in August of 2017. The final rule is undergoing OMB review and is due for publication in the Federal Register in the short term, date yet to be determined.

When the rule was voted on, the

Commission directed the staff to evaluate whether it would make sense for us to come up with a more tailored training and experience approach for different categories of radiopharmaceutical use. We have not made a final determination in that area. We are seeking your input on it. It will be a topic for discussion and vote today and later tomorrow in front of the Commission and probably will receive review by the staff over the next several months. But we are interested in your input, so we hope that you will share your candid opinions on that.

ACMUI, for the audience, has conducted a couple of public teleconferences since the last meeting. There was a public teleconference conducted on February 15th to discuss nursing guidelines and the physical presence requirements for the Leksell Gamma Knife® Icon™. Those reports have been provided to the NRC staff for further consideration. We will touch on those topics here during the meeting today and possibly tomorrow.

The ACMUI also held a public teleconference last week on March 1st to discuss the interim report of the subcommittee on training and experience requirements for various medical

modalities. Again, we'll be discussing that later today with core deliberations to follow in the next few months.

And then other meeting items of high interest for those of you in attendance in the audience or on the phone, later on today we'll have a presentation on the staff's response to recommendations for medical event reporting and on medical licensee patient safety culture, as well as medical projects on the horizon to include the status of molybdenum-99 production. There have been some recent changes in that area.

And then, lastly, the ACMUI Committee members will meet with the Commission at 10 a.m. tomorrow in the Commission briefing room to discuss ACMUI activities, ACMUI comments on training and experience, the ACMUI's comments on changes to the patient release program, and then ACMUI's comments on medical event reporting and patient safety culture.

So we look forward to active engagement with you today, as well as with the Commission tomorrow. And, again, as Doug indicated, we recognize everybody has independent views, so we welcome those views. We hope that you will put

them on the record if not everybody has consensus and that we have an engaging dialogue today.

And with that, I'll turn it over to Ms. Holiday.

MS. HOLIDAY: Good morning, ACMUI members and members of the public who are joining us. You know, I always say this for every meeting and I'll continue to say this; this is the most important presentation that you will hear at the ACMUI meeting. It's your most favorite presentation. I see that everybody is nodding in agreement.

So this is the old business portion of the meeting where we go over the recommendation and action charts from the ACMUI previous meeting and note if there are any status changes. For the last several years, you've always heard me say that, for several years of the charts, they're all tied up with the expanded Part 35 rulemaking. So I'll start off by saying we all were informed at the September 2017 fall ACMUI meeting that the Commission voted on the Part 35 rulemaking and staff, as Ms. Howell indicated, we are still waiting for the final rule to actually be published in the Federal Register.

But with that being said, all of the items in the 2017 chart, with the exception of items 30, 34, and 35, which are noted as delayed, were included in the Part 35 expanded rulemaking. So at this time, I would like to ask the Committee if there's a motion to close these items.

MEMBER ENNIS: Is there any chance that something could change between now and when it's actually published?

MS. HOLIDAY: No. Since the Commission did perform their vote in August of 2017, once the Commission takes a vote, it's the final, done, concluded deal. We're just, at this point, waiting for the Office of Management and Budget to perform their review, and then there are some administrative checks before it actually gets published in the Federal Register. But there will be no additional changes to the rule text itself.

Yes, sir?

CHAIRMAN ALDERSON: This is Dr. Alderson. I have a comment. Just as a point of information for our later discussions, under item number two on that first page, back from June of '07, it has this statement which I just want to remind us about. The rewritten attestation, and

this was requirements for board-certified individuals, should not include the word "competency" but instead should read has met the training and experience requirements. So I just wanted to remind us, as we enter a meeting where I think we may be talking about training and experience requirements, that the word "competency" has been cited here as one that is not to be used widely. So I'm sure we'll use it many times, but I just thought I should remind us that this was there.

MS. HOLIDAY: Thank you. And thank you for pointing that out, Dr. Alderson. What I'd also like to offer is that this recommendation was made 11 years ago, and so none of the members on the Committee now were a part of the Committee back then. And the beauty of having rotating membership terms is that opinions can change. And if the Committee would like to make an amendment to this, you know, that would be captured as a new recommendation.

But I do recognize, since we do have a subcommittee that is looking at training and experience requirements, that this is something that you should keep in mind going forward. So

thank you.

So, yes, I'd like to ask again. Procedurally, this has to be a motion made by the ACMUI.

CHAIRMAN ALDERSON: Is there a second? Second.

MEMBER ENNIS: Second.

MS. HOLIDAY: Okay. Thank you.

CHAIRMAN ALDERSON: Are you going to vote on it? All in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Opposed? None.

MS. HOLIDAY: Great. Thank you. So then that takes us to the 2008 chart. So, again, the majority of these are related to the Part 35 rulemaking. However, I will note that, for item number 5 and item 22, these are related to yttrium-90 microspheres licensing guidance, and I said this at the last meeting, of course, at previous meetings where the Committee made a recommendation that we should move the Perfexion guidance -- I'm sorry. I'm mixing up names. Item number 5 has to deal with the Perfexion guidance, and the Committee at that time, in 2008, asked us to incorporate their recommendations for future rulemaking. The

implications for item 5 are also relevant to item 22 in which the Committee had asked us to move these modalities, these emerging technologies, to be incorporated into the rule.

As I've said previously, some of these technologies, such as Perfexion, such as yttrium-90 microspheres, are captured in 35.1000 licensing guidance, and that's because they have unique features in which they cannot meet all of the requirements in the existing 10 CFR Part 35. As we have also noted that having items captured in 35.1000 guidance allows us to be nimble and make changes as necessary. For obvious reasons, the yttrium-90 microspheres guidance has already been on its ninth revision, with a tenth revision coming out in the near future. So if this was to go into rulemaking, we would not be able to incorporate those changes.

Additionally, the Perfexion™, we just issued the guidance for the Perfexion™ and the Icon™ unit two years ago. So in a similar situation, if this was to have gone into rulemaking, again, we would not have been able to make these changes.

So I have noted that on these charts

they say delayed, but I would like to ask the Committee if the Committee agrees that it should remain as delayed or if you believe that they should simply be closed. VICE CHAIRMAN ZANZONICO: Sophie, this is Pat Zanzonico. Sophie, could you remind us, remind me what the current status of this is? Is it in guidance, and so the idea would be to continue it basically indefinitely in guidance, rather than leaving it delayed because it can't be incorporated into the current rulemaking? So I gather, if it were left delayed, it wouldn't be fully resolved until the next round of rulemaking? Is that basically correct?

MS. HOLIDAY: Correct. So the reason that it is noted as delayed is that staff had accepted the Committee's recommendations in terms of saying that it was not being considered for the current, I don't know if we should say current but the Part 35 rulemaking that was just voted on last year, but that, if this was truly a recommendation, that the ACMUI still wanted staff to pursue, that's why we have left it on the charts. Both the Perfexion™ and Icon™ and the yttrium-90 microsphere brachytherapy are captured in 35.1000 licensing guidance.

So what I'm asking for the Committee is if you, as the Committee, do you agree that this should still be considered for future rulemaking, that is to bring it into the rule text under Part 35, or does the Committee agree that leaving these modalities, these technologies, in 35.1000 space is appropriate? If the Committee believes that it is appropriate to remain in the licensing guidance format, then the Committee would need to make that motion.

VICE CHAIRMAN ZANZONICO: So this is Pat Zanzonico. My suggestion, my personal suggestion is that, since so many things may change between now and the next round of rulemaking, which will be many years in the future we've come to learn, I think, rather than leaving these sort of in limbo pending that, that they should just remain as guidance. And then if and when new technologies, new developments arise between now and the next round of rulemaking, those could be more appropriately addressed at those times, that those issues related to these items could be more appropriately addressed at those times. So my personal suggestion would be to close them and leave them as guidance.

CHAIRMAN ALDERSON: This is Dr. Alderson. I would ask a question then. Since training and experience requirements are a major issue in front of the Committee right now and this is a training and experience issue, what encumbrance would fall upon the Committee if this were left in guidance and we wanted to bring it back out because it fit into some training and experience topic that we were discussing? Is there an encumbrance?

MS. HOLIDAY: Sure. So if I'm understanding correctly, the question is if the Committee were to make recommendation and staff were to adopt the recommendations or pursue other venues with training and experience, how would that affect these 35.1000 licensing guidance documents? Essentially, licensing guidance under 35.1000 are considered customizable licensing conditions, and that simply means that what's in the guidance is separate from what's under the Part 35 rule, since they could not meet all of the provisions under 35. So we could have different training and experience requirements for these technologies that are licensed under 35.1000.

Some of you on the Committee may recall

the radioactive seed localization guidance that was recently issued a few years ago and the subcommittee had provided recommendations. The training and experience for that was very different from what is captured under the rule for brachytherapy users, and that is to say that we also have a provision in there that notes the ability for surgeons to perform, you know, the extraction of the seeds under the supervision of the AU. So for things like that, you would want that to reside in 35.1000 space.

So we made changes in the rule to accommodate, you know, training and experience. However the Committee or the staff decides to move forward, that would not affect the training and experience in that guidance. It would not affect the training and experience in the Y-90 guidance and so on and so forth.

If we were to agree to make the changes for those particular technologies, then another revision to the guidance would occur, and we'd be on say revision 11 of the Y-90 guidance.

CHAIRMAN ALDERSON: So if I can rephrase that into the words I used, there would really be no encumbrance to approving this as it is

and leaving it in guidance.

MS. HOLIDAY: Yes. I see a hand.

DR. HOWE: This is Dr. Howe. If you change the guidance and that guidance in training and experience now covers what's in a particular 35.1000, the 35.1000 guidance could be revised to remove the specific training requirements that are now incorporated in the rule. Now, training and experience is a very important part of the 35.1000 uses, but it's not the only part. So you still would have, you still may have different parts of the guidance that would stay if the training and experience might go into the rule if you make changes.

CHAIRMAN ALDERSON: Yes, good. So it doesn't seem to provide any problem but some latitude for practitioners.

MS. HOLIDAY: Correct.

CHAIRMAN ALDERSON: Good. Okay. So can we hear the motion again, or are there further questions or comments? The motion again is that --

MS. HOLIDAY: I believe the motion is to close items 5 and 22.

CHAIRMAN ALDERSON: Yes.

MS. HOLIDAY: So the motion was made by

Dr. Zanzonico.

CHAIRMAN ALDERSON: And moved and seconded. Okay. Further discussion? Yes, Dr. Palestro?

MEMBER PALESTRO: Yes, I have a question. If these items are closed out, let's see if I can figure out how to phrase it properly, if they're closed out, they essentially disappear from the log and we're not going to review them again. So going forward in the future, all of us are gone from this Committee, how will future members recognize that these were items of concern at one time?

MS. HOLIDAY: Well, unfortunately, they would have to go through many years of transcripts, not that that's the most wonderful task either. But, essentially, they would not know that these were past items because we don't, once we close them on the charts, again, they do disappear off the charts, just like how you know we have a two and then a five but there's no one, three, or four.

MEMBER PALESTRO: So that would be my concern then. If we leave it as is, where it says open and delayed, in the future they can be flagged as areas to be revisited.

MS. HOLIDAY: Yes, it could be revisited in the future if that's what, if that's what the Committee wishes for future members to be able to do. But the Committee now has the opportunity, as members on the existing Committee, to make a decision. If you feel like this does need to stay as a delayed for future members to consider, it's at your discretion.

Mr. Green?

MR. GREEN: So this is from the 2008 year, so the guidance has been static for a decade? And if there are ever changes in the technology, I think we can go back and change the guidance. I'm not sure if there's a need to keep it currently on the list to remind us it hasn't been changed in a decade. But we can go back and change that guidance, could we not?

MS. HOLIDAY: That's true, just as the ACMUI formed a subcommittee, and I think Dr. Metter chaired that subcommittee to review the staff's draft revisions to the guidance, again, once the guidance comes up for another revision or if the Committee identifies that other things need to change in the guidance, just with any other recommendation, the Committee is able to make that

recommendation at the meeting and it's captured on the charts going forward. CHAIRMAN ALDERSON: With respect to Dr. Palestro's comment, I would think that, I understand your point exactly, but if, in fact, this is a practice issue, if practitioners are concerned about this, it will be known to us. They will bring it up. If no one is concerned, we may forget about it, but then we don't need to worry about it. But if there are issues in practice, they could bring it back and we just heard that we would have the ability to change this or do whatever we want. So I think that the motion to close is not inappropriate at this time.

MEMBER WEIL: Laura Weil. I think what Dr. Palestro is getting to is something that concerns me, as well, is the lack of institutional memory on this Committee. We don't really have an accessible history. And given the nature of rotation, perhaps this is not the place for that history to be maintained, but transcripts are an extremely unwieldy way to access that history. And we struggle in subcommittee work sometimes to figure out, well, why 700 hours, why, you know, any number of things that come up. And I think we need some sort of record, that I'm not aware of anything

exists other than transcripts, in order for us to do our work more efficiently.

MS. HOLIDAY: So I understand the crux of what you're trying to say. So if I may offer this, I will take this as an action item that I will -- because I don't delete, I don't delete past recommendations. They're just hidden on the Excel spreadsheet. So what I will do is I will open up all of the last 11 years of charts, and I will capture them, I will add them to the ACMUI's history web page on the ACMUI website so that both ACMUI members and members of the public will be able to access past committees' recommendations, if the Committee will accept that action.

MEMBER PALESTRO: Yes, I just want to say that I share Ms. Weil's concerns. And we found the problems with institutional history in the Training and Experience Subcommittee, and I think your suggestion is a good one, as long as there a way for someone or some committee to go back in the future and look things over and have a sense of what went on and so forth, and what was considered important may or may not still be. So I think --

MS. HOWELL: And we appreciate your input on that. So it's not really that the

information is lost. It may not be as transparent to you, as Committee members that you would like. But I think certainly what Ms. Holiday just proposed would satisfy that concern so that it would be readily capture-able by all the Committee members.

CHAIRMAN ALDERSON: Does the NRC need a vote on this suggestion, or can this just go forward?

MS. HOLIDAY: No. NRC doesn't need a vote for me to take the action. What I'm still waiting for is, given this action, does the ACMUI still second Dr. Zanzonico's motion to close these two items.

CHAIRMAN ALDERSON: Right. So we still have the motion on the table to close these two items. Is there further discussion on that? Hearing none, we'll vote. All those in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Any opposed? None. It passes.

MS. HOLIDAY: Thank you. Okay. So, again, for items 2, 19 -- no, 2 and 28, 29, 30, those are all related to the Part 35 expanded rulemaking. Very similar to the 2007 chart, I'd

like to ask if there's a motion to close those items, not the ones that say delayed but items 2, 28, 29, and 30.

CHAIRMAN ALDERSON: Is there a motion to that effect?

MEMBER PALESTRO: So moved.

CHAIRMAN ALDERSON: Dr. Palestro. Is there a second? Is there discussion? All in favor? Any opposed? No opposition.

MS. HOLIDAY: Thank you. Again, so for the ones that do say delayed, such as number 19, number 26, and number 27, those were delayed, so I will keep those on the chart because they were not included in the Part 35 expanded rulemaking.

Okay. So that brings us to 2009. There are only two items on this chart. Again, these were included in the current Part 35 expanded rulemaking. I will note, of course, that number two has to deal with the 35.390 written directive, not the training and experience. But I know, since 35.390 is something that's being considered by the Committee now, I would like to point that out.

But, again, similar to the 2007 and 2008 chart, these are tied with the Part 35 expanded rulemaking. So is there a motion from the

Committee to close these two items?

CHAIRMAN ALDERSON: Do I see a motion?

VICE CHAIRMAN ZANZONICO: So moved.

CHAIRMAN ALDERSON: Second?

MEMBER PALESTRO: Second.

CHAIRMAN ALDERSON: There is a second. Is there discussion? All in favor?

(Chorus of ayes.)

MS. HOLIDAY: Thank you. Okay. Again, the 2010 chart, all the items were closed on that, so that's not included in this packet. For year 2011, item 1 has to deal with the patient release criteria. As you heard from Ms. Howell earlier in her remarks, staff issued its patient release paper to the Commission on January 29th, so this is not an open item anymore. The ACMUI's recommendations as it relates to patient release was captured in the subcommittee report that was unanimously endorsed by the Committee included as Enclosure 4 for that patient release SECY paper. So I would like to ask at this time if there's a motion to close item 1.

CHAIRMAN ALDERSON: Is there a motion?

VICE CHAIRMAN ZANZONICO: So moved.

CHAIRMAN ALDERSON: And a second? Any

discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: It passes unanimously.

VICE CHAIRMAN ZANZONICO: Sophie, I have a parliamentary question. Can the Chair and Vice Chair make motions? On some committees they can't. On this committee can we?

MS. HOLIDAY: NRC does not preclude you from making motions. Okay. Item 6 is an item that's open indefinitely. This is where staff will review the reporting structure with the Committee on an annual basis. You'll hear that presentation from me later on this morning.

Items 11 through 15 are all related to the expanded Part 35 rulemaking. So, again, I'd like to ask if there's a motion from the Committee to close items 11 through 15.

CHAIRMAN ALDERSON: And is there a second? Is there discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Thank you. Item 16 again has to deal with patient release criteria similar to item 1. The patient release Commission paper

was provided to the Commission on January 29th, and is there a motion to close item 16?

VICE CHAIRMAN ZANZONICO: I make a motion.

CHAIRMAN ALDERSON: Is there a second?

MEMBER DILSIZIAN: Second.

CHAIRMAN ALDERSON: Is there discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: It passes unanimously.

MS. HOLIDAY: Thank you. All the items on the 2012 chart were closed, so that chart is not included. For the 2013 chart, all of these were related to the Part 35 expanded rulemaking. That was the time that the ACMUI was provided with the draft proposed rule, so all of these items again are related to the Part 35 expanded rulemaking. Is there a motion to close all of these items?

CHAIRMAN ALDERSON: There's a motion and a second. Is there a discussion? Hearing none, all in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Thank you. Okay.

There's no 2014 chart because all of those items were closed. So that brings us to the 2015 chart. I apologize if it's very hard to see. Item 7 has to deal with the abnormal occurrence criteria. I believe I informed the Committee at the meeting in September that the NRC issued its revised abnormal occurrence policy, so this item should have been closed, but I do not believe that we made a motion during the September meeting to close it. So at this time, I'd like to ask if there's a motion to close item 7.

CHAIRMAN ALDERSON: So is there a motion to close? There is a motion. Is there a second? There's a second. Discussion? Seeing none, all in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: It passes unanimously.

MS. HOLIDAY: Thank you. Items 12, 13, and 15 are related to the Patient Intervention Subcommittee. As you'll recall during the September 2017 ACMUI fall meeting, the Patient Intervention Subcommittee provided a revised report which was incorporated into the medical event reporting and its impact on Medical Licensee

Patient Safety Culture Subcommittee report as an addendum, I believe, or an appendix. So at this time, I would like to ask the ACMUI if there's a motion to close items 12, 13, and 15 as they were superseded by the subcommittee's report provided in 2017.

CHAIRMAN ALDERSON: Is there a motion? And a second? Is there discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Thank you. Again, item 22 is related to the abnormal occurrence criteria that was revised last year, similar to item 7. Is there a motion from the Committee to close item 22?

CHAIRMAN ALDERSON: Is there a motion?

MS. HOLIDAY: Dr. Suh.

CHAIRMAN ALDERSON: And there is a second. Thank you. We have a motion and a second. Is there discussion? Hearing none, all in favor.

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Thank you. Okay. For 2016, this, of course, was when the Committee was provided with the draft final Part 35 expanded rulemaking, so items 1 through 15 are related to

the ACMUI's recommendations as it relates to the Part 35 expanded rulemaking. Is there a motion from the Committee to close these items?

CHAIRMAN ALDERSON: Is there a second? Is there discussion? Hearing none, all in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Thank you. Item 16, Dr. Alderson formed a subcommittee to review the training and experience requirements for all modalities under 10 CFR Part 35. This I will leave open since that subcommittee is still performing its reviews and currently is reviewing the requirements for 35.300 users.

CHAIRMAN ALDERSON: So I would, I think that's appropriate. I would suggest possibly, I noted back on item number 6 in the year 2011 it contained the words open indefinitely, so it just kept coming back. And that was one of the things that we proposed and talked about when we created this Committee, the idea that, as medicine evolves, the world evolves, that it was always important to be re-evaluating training and experience requirements. So I would suggest perhaps that we include not just open but open indefinitely under

that as a phrase in this particular handout. Yes, Ms. Weil?

MEMBER WEIL: Thank you. In support of that, I'd say that we called it a standing subcommittee, rather than simply a subcommittee.

MS. HOLIDAY: Yes. So my understanding is that it was originally named standing subcommittee, but, as noted in the ACMUI charter, ACMUI does not have any standing subcommittees. And I believe the idea was that this subcommittee would review the training and experience requirement on a as-needed basis, maybe every five years or so, however long it took to get through it, because you didn't want to continuously have to look at the training and experience requirements every year. I wasn't involved with the meeting at that time, so I'm not very sure if that was the intent of the subcommittee.

CHAIRMAN ALDERSON: Well, Dr. Palestro can speak. I will say that my intention in talking about it was that it would be reviewed on an almost continuous basis so that we were keeping up with what was happening in the field. Dr. Palestro?

MEMBER PALESTRO: Yes. The concept was not necessarily that it would be a yearly review or

a monthly review but that it would be an ongoing review every X number of years and whenever it was deemed necessary, perhaps the introduction of a new technique, a new radiopharmaceutical, that sort of thing. And so that was the concept of forming a standing subcommittee, in essence that its work was never really complete.

MS. HOLIDAY: Okay. So I will offer that I am not opposed to this being open indefinitely. I would like to say, while we called it a standing subcommittee, I would make this similar to our Medical Events Subcommittee that reviews medical events on an annual basis. We don't refer to that as a standing subcommittee, but that review is performed on an annual basis. So I would like to refrain calling it a standing subcommittee, but I will note that the Committee will review this on a continual basis. Is that amenable to the Committee?

MEMBER PALESTRO: It is to me, yes.

CHAIRMAN ALDERSON: All in favor? That's a consensus if that would be true. There are comments, though, however.

MS. HOLIDAY: I agree.

CHAIRMAN ALDERSON: All in favor of

that?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Yes, everyone is. So, yes, that's fine. Thank you.

MS. HOLIDAY: Okay. Item 24 has to do with the Committee reaching out to their respective professional organizations to enhance the communications between the ACMUI, the NRC, and the medical community. I've left this open because I believe that this is one of those open indefinite items that the Committee put forward as a recommendation.

CHAIRMAN ALDERSON: It did.

MS. HOLIDAY: So if it's okay, is there a motion to amend this to say open indefinitely?

MEMBER PALESTRO: So moved.

CHAIRMAN ALDERSON: Is there a second?

VICE CHAIRMAN ZANZONICO: Second.

CHAIRMAN ALDERSON: Any discussion? All in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: It's unanimous.

MS. HOLIDAY: Okay, great. Items 39, 42, and 43 are related to the yttrium-90 microspheres licensing guidance. I suggest leaving

this as open because staff has not issued its revision to the Y-90 guidance. As you may be aware, we issued the guidance for public comment and that public comment period ended earlier this year. Just this month. So when the next draft revision of the guidance is ready, it will be provided to the ACMUI for its review and comment at that time. So I will leave items 39, 42, and 43 on the chart as is.

Okay. Items 44 through 52 are related to the Committee's recommendations for the NorthStar's licensing guidance. I have these noted in red, and I wrote closed, although this has not been put forth as a motion to the Committee yet. Staff issued this licensing guidance last month on February 8th. It was sent out on the medical list server. I will provide it to the Committee hard copy before you leave for the meeting.

Since that guidance was issued, staff will, in the near future, issue a memorandum to the Committee to explain which recommendations from the Committee were accepted and were not accepted or partially accepted to explain what staff did in response to your recommendation.

So at this time, I'd like to ask if

there's a motion from the Committee to close items 44 through 52.

MEMBER ENNIS: It seems to me we should wait and see that document before we close it.

MS. HOLIDAY: The guidance has already been issued, so, similar to, like, the AO criteria being revised by the Commission or the Part 35 expanded rulemaking, it's already been issued. So staff has already addressed the ACMUI's recommendations. All that staff has to do at this point is simply issue the memorandum to explain what we did with your recommendations. Ms. Weil?

MEMBER WEIL: I support the suggestion that we wait. If this is inconvenient for you, perhaps you should have communicated all that stuff to us prior to asking us to close it.

MS. HOLIDAY: Sure. That's not a problem. Is there further discussion from the Committee?

MEMBER PALESTRO: Just a question. In terms of the ACMUI recommendations, were they all accepted in their entirety or were some of them accepted partially and so forth, the way we see in some of the other --

MS. HOLIDAY: I would have to defer

that to Dr. Howe or Ms. Ayoade, as that was their working group.

DR. HOWE: This is Dr. Howe. I'm not prepared right now to give you an answer to that question.

CHAIRMAN ALDERSON: So I think the sense of the Committee is that we're not ready to close all these items and Dr. Howe isn't ready to comment to us on our questions. So I think these items should remain open. Does anyone wish to say otherwise on the Committee? The Committee's recommendation is that they remain open.

MS. HOLIDAY: Okay.

MR. BOLLOCK: This is Doug Bollock. And I'll just add, whether you close it or not, if you are not satisfied with our responses, whether we accept it partially, fully, or not at all, and when you see those responses, that doesn't preclude you from, in the future, giving other recommendations for future updates, revisions, to the guidance.

VICE CHAIRMAN ZANZONICO: So this is Pat Zanzonico. So this is the guidance that was issued in February?

MS. HOLIDAY: Yes.

VICE CHAIRMAN ZANZONICO: That's considered final and presumably has addressed, but we can't definitively say at the moment, but presumably has addressed the ACMUI comments. But that's the document we're referring to, the February guidance.

MS. HOLIDAY: Correct, correct.

MEMBER DILSIZIAN: Just to reassure you, I mean, I was responsible for this document and all the comments in the red are the ones we recommended but cannot firmly state that all of them weren't adopted. I just wanted to show you that these are correct.

CHAIRMAN ALDERSON: This is Dr. Alderson. Administratively speaking, I understand that it's an efficient action now to potentially close these because some of this has already happened. On the other hand, from the point of view of the public and we, as an advisory committee, represent the public to the agency, it looks as if we close something before we know what happened and perhaps we don't really, aren't really caring about it that much.

So I think, from the standpoint of the Committee's representation of the public, that it's

reasonable to keep these items open.

MS. HOLIDAY: Sure. I accept that. Are there any other comments for these items? Okay. So then we can move on to the 2017 chart. Okay. For the very first item, this is where the Committee requested that we review staff's response to all the Committee's past recommendations and actions as it related to the Part 35 rulemaking during the fall 2017 meeting. As I stated earlier, we were closing the items related to the rulemaking efforts earlier.

NRC has not issued the final rule yet. However, in 2018, because the rule will have already been published by the next meeting, staff will have an agenda item to go through each of the recommendations from the ACMUI from 2007 and forward, including the reports from 2013 and 2016, to give you that detailed review.

So at this time, I would leave item 1 as pending to be discussed at the fall 2018 meeting. Is that okay with the Committee?

CHAIRMAN ALDERSON: It seems so.

MS. HOLIDAY: Okay. Item 8 has to deal with the Patient Intervention Subcommittee amending their report and providing it during the fall of

2017. And as I discussed earlier, that report was provided in a presentation and included in the reporting and its impacts on Medical Licensee Patient Safety Culture Subcommittee report. So I would like to ask if there's a motion to close this item since the item itself is just saying that they will amend their report and present it, which has already occurred during the September meeting.

CHAIRMAN ALDERSON: Is there a motion to that effect? A second? Several seconds. Is there further discussion? Hearing none, all in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Okay. Item 12. This was the item where the ACMUI asked staff to engage with the Organization of Agreement States to find a way to centralize reporting from the agreement states. This was noted during Dr. Ennis's report where the Committee conducts their annual review of medical events reported on a fiscal year basis, and the Committee noted that there were discrepancies between how various agreement states report their information and how some events do not provide timely updates.

So at this time, I would like to inform the Committee that, during our monthly phone call with the Organization of Agreement of States and the Conference for Radiation Control Program directors, I gave a presentation or I made a note to the agreement states that this was an issue that was recognized by the ACMUI and that we are reminding the agreement states that they need to report their medical events in accordance with FA-300, which is the procedure that informs the agreement states how they have to report medical events. In addition to that, I informed the states that they need to ensure that they provide timely updates so that the information may be appropriately captured in that.

So at this time, I would like to propose or ask the ACMUI if there's a motion to close item 12. CHAIRMAN ALDERSON: Is there such a motion?

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico. Is there any evidence since your presentation if they are or are not reporting in a more timely manner?

MS. HOLIDAY: Because medical events are reported as the medical events happen, there's

no way for me necessarily to double check all of the 37 agreement states because events aren't continuously reported. Some states have events, and some do not. So I guess a turning analysis will be able to tell by next year if that's the case.

MR. BOLLOCK: This is Doug Bollock. So we do a, we review NMED events for the previous year every year, and we just did that for 2017. So there wasn't time to see that or see any difference in the reports or doing a review of NMED at this time. There just hasn't been enough time to see any gains from the discussion we had with the agreement states.

MEMBER ENNIS: Another question is, and I guess maybe this is for you, I think, has the role of, okay, what do I do? And since you've done that, it would make sense to come off. I think, for me and maybe for us, it's a little bit of like, all right, what are our active issues and help refresh our memory in case, because we're busy doing other things a lot of the time. And this feels to me like still an active issue in my mind. Okay, has this worked and this may become a bit of an ongoing thing. So on that side, I'm inclined to

prefer to have it still remaining on the list.

CHAIRMAN ALDERSON: Okay. So there's a suggestion from Dr. Ennis, for those reasons, this should remain open. We still don't really have a motion to close it. Is there a motion?

VICE CHAIRMAN ZANZONICO: This is only a comment. Obviously, we've had items open dating back to 2008, so I think leaving a 2017 item open a little bit longer isn't that onerous.

CHAIRMAN ALDERSON: Zoubir?

MR. OUHIB: Yes. I guess keeping it open probably won't be very beneficial because it will either confirm that the system is actually working or maybe the ACMUI will have other suggestions or recommendations perhaps to meet whatever needs to be met, in my opinion.

CHAIRMAN ALDERSON: So it seems that the sense of the Committee is to keep this recent item open. Is that generally the feeling of the Committee? The heads are nodding yes, so I believe this will stay open. MS. HOLIDAY: Okay. Then that brings us to items 13 through 20, and they are related to the recommendations that came out of the medical event reporting and its impacts on medical licensee patient safety culture. We

should really come up with an acronym for this. You will hear a presentation later on today from Mr. Bollock to explain staff's response to some of those recommendations. So at this time, I will leave those items open on the charts.

Okay. So then that brings us to item number 21. This has to deal with the Nursing Mother Guidelines Subcommittee report. So the initial report was discussed during the September 2017 fall ACMUI meeting with the suggestion that some amendments be incorporated and that this be discussed at a future date. So we did hold that public teleconference on February 15th. So I have this marked as a closed item because the action was to hold a public teleconference, which we did do on February 15th.

So, again, I prematurely marked closed, so I would like to ask the Committee if there's a motion to close this item.

MEMBER METTER: I meant to close that item.

CHAIRMAN ALDERSON: Is there a second?

MEMBER O'HARA: Second.

CHAIRMAN ALDERSON: There's a second. Is there further discussion? Hearing none, those

in favor of closing this item?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Okay. And item 22 through 28 are related to the Patient Release Subcommittee's report. Again, staff issued its paper to the Commission on January 29th. I provided the ACMUI with a copy of that Commission paper, as well, if you'd like to see it in hard copy. Again, essentially, the subcommittee endorsed by the full committee agreed with staff's conclusions that no changes were warranted via rulemaking under 3575. So I would like to ask the Committee if there's a motion to close items 22 through 28 as they relate to the patient release Commission paper.

VICE CHAIRMAN ZANZONICO: Motion. So moved.

CHAIRMAN ALDERSON: Is there a second?

MEMBER ENNIS: Second.

CHAIRMAN ALDERSON: Discussion? Hearing none, all in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: Thank you. Okay. Item

29 has to deal with the physical presence requirements for the Leksell Gamma Knife® Icon™ Subcommittee report. Again, this item was to hold a public teleconference in the near future to discuss the amended report. Similar to the nursing mother guidelines, we held that public teleconference on February 15th, so I'd like to ask if there's a motion to close this item as the committee did hold its public teleconference on the 15th of February.

CHAIRMAN ALDERSON: Motion was made by Dr. Suh. Is there a second? There are seconds. Further discussion? Hearing none, all in favor?

(Chorus of ayes.)

CHAIRMAN ALDERSON: Unanimous.

MS. HOLIDAY: And then item 30 is that we agree to hold the spring ACMUI meeting on March 1st and 2nd with a backup date of March 14th and 15th. We did not meet either of those dates, but we are here on March 7th and 8th. So I'd like to ask the Committee if there's a motion to close item 30.

CHAIRMAN ALDERSON: This one should be easy. With seconds, yes. Further discussion? Hearing none, approved.

MS. HOLIDAY: Thank you. Okay. And this brings us to the 2018 chart. These recommendations come out from the February 15th public teleconference. Items 1 through 2 are related to the recommendations for the Nursing Mother Guidelines Subcommittee report. However, I have left them as open items as I believe the intent of the ACMUI was that these recommendations be considered for changes in Regulatory Guide 8.39, which is the guidance for patient release.

So I don't see any shakes of heads. Is the --

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico. The Nursing Mother Guideline Subcommittee report is going to be amended, is going to be revised. MS. HOLIDAY: Absolutely.

VICE CHAIRMAN ZANZONICO: So on that basis alone, these items should be left open.

CHAIRMAN ALDERSON: Yes, that's right. I agree.

MS. HOLIDAY: Okay. Mr. Green?

MR. GREEN: On number one, I see that some references are made merely to nuclides, carbon-11. Some references are made to compounds,

I-123 sodium iodide. And then some, again, go back to I-131 sodium iodide and -- so there's a blending of nuclide and chemicals. But, for example, I-123, iofetamine, not iofetamine, MIBG is not on the list. Sodium iodide 123 is, but there are other 123 compounds that are omitted from this list.

VICE CHAIRMAN ZANZONICO: This is Pat Zanzonico. I think this list may not reflect completely the tabulation in the report. And you're right. In some cases, the recommendations, the guidelines were based, were radionuclide specific. So for example, if the physical half-life was short enough that the biological half-life of the radiopharmaceutical was irrelevant, then it was a radionuclide specific guideline. On the other hand, if the effective half-life was impacted by both the physical and biological half-life, then they were radiopharmaceutical specific guidelines. So that's why there's a mix of guidelines, some radionuclide specific, some radiopharmaceutical specific. But I don't think this list in the table reflects the report exactly.

MEMBER METTER: This is Darlene. I think what happened is, like, these were the items that were brought to the attention of the Committee

at the time and not the items that were on, the other items that were on the list.

MS. HOLIDAY: Okay. So then if there's no further discussion, we can move on to the next items. Items 3, 4, and 5 are related to the physical presence requirements for the Leksell Gamma Knife® Icon™ Subcommittee report. These recommendations were presented during the February 15th public teleconference. I've left these items open on the agenda. As Ms. Howell indicated, this report was provided to staff specifically. There's an NRC/Agreement State working group. I'm the co-chair of that working group, and we are considering the ACMUI's recommendations during our review and evaluation to determine if there should be changes to the physical presence requirements for either the Perfexion™ or the Icon™ unit. So I've left these items as open.

Okay. So these are all of my items on the old business charts. Are there any additional questions, comments, or concerns?

CHAIRMAN ALDERSON: Seeing none.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Thank you. Excellent report. So that brings us to the open

forum, medical topics of interest for further discussion. We've actually been discussing some of those as we went through these items. And we're already well behind time here. So are there any other new medical topics of interest that people would like to discuss further before we invite Dr. Howe to come forward? Seeing none -- oh, Dr. Palestro?

MEMBER PALESTRO: Very quickly. With respect to communications with professional organizations, we did submit a request for a continuing education program at the annual meeting of the Society for Nuclear Medicine and Molecular Imaging, similar to what we did last year. We have not yet heard back. The meeting is later in June this year, so I would hope that we find out shortly.

We also had intended to submit to the ACR but the format of that meeting changed and this type of program doesn't fit with what they're going to do this year.

CHAIRMAN ALDERSON: That's good. We have a comment from the audience.

MS. KUBLER: Hi. Caitlin Kubler with the Society of Nuclear Medicine and Molecular

Imaging. I just heard from our meeting staff this morning, we will be sending out those confirmation notices next week.

CHAIRMAN ALDERSON: Thank you. Hopefully, you'll get a positive one. Any other comments? Hearing none, I think we're ready to move forward to the next portion of the program, the next agenda item, which is medical related events. Dr. Howe.

DR. HOWE: All right. This is one of my favorite parts of addressing the ACMUI. We'll be talking about the medical events that happened in fiscal year 2017. Not only will you have slides, but members of the ACMUI will have the printout from the NMED reports for this time frame.

This is just a reminder that there are many more medical procedures given, and the number of medical events that you see is just a very small number of those procedures. So we also have a dose threshold for diagnostic events, and that precludes most diagnosis events that don't go as expected from not meeting the threshold from that event. And there are about 150,000 therapeutic procedures performed using radioactive materials in a year. So those are kind of very rough numbers for your

denominator.

The ACMUI wanted a perspective, how are the medical events trending. And as you can see for 2012, '13, '14, the number of medical events was 48, 43, 46. That's not a very large number. We're comparing that to 150,000 per year. And for diagnostic, there's a million. But with our dose limit, you see very few diagnostic.

And then I've broken down how those medical events, what categories they fell into. 35.200 are the imaging and localization. Those are your diagnostic events for the most part. 35.300 are your therapeutic or I-131 greater than 30 microcuries. All of those require a written directive. 35.400 are your brachytherapy, primarily manual, permanent implant, and temporary implant. And 35.600 are your high dose remote afterloaders, new teletherapy units, and your original gamma stereotactic radiosurgery units. And 35.1000 includes the things that we consider to be other than 100 through 600. Most of the 35.1000s are going to be the yttrium-80 microspheres, but it may also include intervascular brachytherapy, the Perfexion™, the Icon™, and a few other devices.

So next slide. So this is what we've seen in the last three years. 57, 50, 43. Once again, you're not seeing very large numbers. They fluctuate, around the mid-40s and they go up into the 57 sometimes, up in the 50s. And you can see down below the change in the different modalities that had medical events. The parentheses that I provide are the number of patients, so we may have had nine -- and the other thing is how do we count medical events? We basically count them by facility. If a facility has a medical event, they report it to us. That medical event, because they may have an event today and then they go back through their records and they find out that they didn't catch additional medical events earlier. So we may have more than one patient for a medical event, but most of our medical events are single patient activities.

So you can see in 2015, we had nine medical events for 35.400, which is brachytherapy. We had ten patients, so one of those medical events had two patients. And when you look at 2017, for 35.600, we had eight, I won't say there are eight facilities because if a facility reports a medical event today and then they report another medical

event two months from now, we will count those as separate reports. So in 2017, we had eight reported medical events that ends up at one facility had two different reports, and they had a total of -- and then one location had five patients and the other had four patients. So you see more patients than you have events.

Next slide. So let's start looking at the specific modalities. So we had no medical events in 35-200, which are primarily the diagnostic, technetium events. We had four in 35.300, which require written directives. Three of those for iodine-131, and we had one for radium-223. And this looked specifically at the events.

Next. So for I-131, the first event I'll be telling you about, the facility administered two millicuries of I-131 when none was prescribed. The physician asked for parathyroid tests, but, instead, the facility gave a thyroid scan. There was no written directive. We have seen this in the past where activities that require written directives are given without written directives, and that goes back to the facility and its being aware of what written directives require and being able to, they should identify this before

they ever gave it because they should have said where's the written directive. There was none. Well, I shouldn't be giving I-131 in two millicurie quantities if there is no written directive. So these things should be caught earlier because they should have triggers.

What they did was they did electronic ordering, and the record system was used without confirming the order prior to administration. And the thyroid received 1600 centigray.

What have they done to corrective actions? They've modified their procedures. They're going to confirm the dosage orders, and they are retraining personnel. Those are common corrective actions that we see.

The next slide. In this case, they administered 20 millicuries instead of 30 millicuries that was in the written directive. In this particular case, the written directive was incorrect. The written directive should have been written for 20.2 millicuries, but, instead, they wrote it for 30. So the intended dose was given. And now, as a corrective action, they're requiring more individuals to review the written directive for accuracy before signing it and giving the

administration.

Next slide. They administered 106 millicuries instead of 150. This is a typical problem we see over and over again. The dosage was delivered in two capsules. The patient shook the vial into the mouth but only one capsule came back. The other was left in the vial. And it wasn't discovered until the vial was sent back to the pharmacy and they did a measurement and determined they still had I-131 inside.

Next slide. This is our radium-233 dichloride issue. In this case, they administered more activity than they were supposed to. They administered 176 microcuries instead of the 108 microcuries. How did this happen? They had two patients they treated on the same day. They correctly labeled with the patient names the lead pigs and the syringes, but they gave the wrong syringe to the physician when they were giving administration or to the technologist when they were giving administration. So this is a wrong patient.

They've added a time out. They've now, for corrective action, the dosing physician has to verify the identity of the patient and the

prescribed dose in the written directive. And you'll see later, when I get to some of the yttrium-90 microsphere medical events, that time out doesn't always work. So it is a corrective action that many licensees give, but it doesn't always work.

Next slide. So now we'll move into the 35.400. These are the brachytherapy, both permanent and temporary implants. So we had seven medical events. All of them were prostate medical events. And you'll see, as I go through, we had one licensee with two reports. They had a human error and one they attributed to anatomy. They had a wrong site. They used a previous activity. And then they had larger than the pre-plan or the swelling and had three cases of those.

And now let's look at the individual cases. Next slide. In the first one, the licensee, they had one licensee but two separate reports. In the first case, the patient received 62 percent of the dose. There was no root cause, but they attributed it to human error. And they made a statement that some seeds may have migrated, but they didn't provide any additional verification of why they believed that was true.

Next slide. It's the second case. In this case, the patient received 78 percent of the prescribed dose, and they blamed it on patient anatomy. They identified during post-implant CT scan and subsequent dosimetry. It was identified during the post CT scan and subsequent dosimetry analysis. There was a delay in reporting to the state due to communication breakdown and inadequate procedures.

And the next slide. Now we go into the patients, additional ones. In this particular case, there's the wrong site. They said they received 74 percent less than prescribed, but if you look you'll see almost all of the dose went to the penile bulb, so they delivered it to the wrong site. And they attributed it to human error, and they are providing additional training to personnel and approved supervision.

CHAIRMAN ALDERSON: Is there a typographic error on that slide?

DR. HOWE: There might be. Which --

CHAIRMAN ALDERSON: It says proceed 2,760 instead of 1100.

DR. HOWE: Oh, there should be another zero there.

CHAIRMAN ALDERSON: Right. There should be another zero.

DR. HOWE: Yes.

CHAIRMAN ALDERSON: Let's note that and we'll add that in.

DR. HOWE: Okay.

CHAIRMAN ALDERSON: Thank you.

DR. HOWE: Thank you. The next slide. Okay. In this particular case, there was an over-dosage where the patient received 157 percent of the prescribed dose, and how did this happen? Well, they failed to enter the correct activity proceed into the physics spreadsheet. They had a value from the previous calculation, and they didn't put the new value in. So they didn't perform an independent verification of the treatment data. The new action is a secondary hand calculation. They're required to use a blank spreadsheet, so they don't carry erroneous information from previous calculation. And they are going to have a verbal timeout to verify key parameters prior to treatment.

Next slide. This is an underdose, and they attributed the underdose to an 18-percent increase in the prostate size compared to the pre-

plan and that the physician had planned to have a cooler coverage at one part of the prostate, and that led to an under-exposure. And it was discovered during a routine audit conducted by the medical physicist.

Next slide. They were prescribed 14,500. They received 10,000 centigray. It was administered in December. It was discovered the next day. The second treatment was planned for the day after where they implanted eight more seeds, and they attributed it to post-operative swelling and seed migration. And they decided that a corrective action was to perform the post-implant imaging sooner than one day later to minimize the effect of swelling of the prostate gland and possible migration of seeds.

Next slide. In this one, they prescribed 1400, 1450 centigray, and they received 10,353 centigray. They determined that they should order additional seeds beyond what the pre-plan requires. I think when they were inserting them, they realized they needed more coverage. And then they performed a post-implant x-ray and ultrasound to determine if and where additional seeds could be placed.

In the next slide, now we're moving on to the 35.600, which are the HDRs, the teletherapy and the Gamma Knife. And in this case, we have seven gynecological HDR events, and we have one Gamma Knife event. And the gynecological ones, we had more patients than we had reports and also we had most of our additional patients came with a software issue. And we also had wrong site before, equipment failure for one.

So if we move to the next slide. This was a generic software issue, and this is a generic software issue that we shared with the FDA under our NRC FDA MOU. In this particular case, we had two licensees and we had a Part 20 report. And the first licensee, there was a determination made that the Oncentra software versions, both 4.5, 4.5.1, and 4.5.2, had an issue with source step size when you were using a ring. In this case, the source step size of 5 millimeters was a default, that if you put 2.5 millimeters in you were still going to get 5 millimeters. And so licensees weren't able to really see what was happening in this case.

So in the first case, we had four patients. The dose to the unintended site ranged

from 2,800 centigrade to 1,400 centigray. The dose to the unintended site was expected to be between 126 to 175 centigray per fraction. So we clearly have a medical event for the wrong treatment site.

Elekta notified software users of the problem with the ring. The initial software problem was identified overseas in France, and then Elekta put a notification out and this caused a number of licensees to go back and check to see if this was a problem for their particular patients and if they had used the ring.

On the next slide, this is our second licensee, and this particular licensee had five patients. It was a problem with the Oncentra software version 4.5.2. And it was, again, the software step size with a ring of 5 millimeters versus 2.5 millimeters. In this case, when you go 5 millimeters, you may actually go back over and cover tissue that you had only intended to give one dwell time. And then you have doses to another side of the ring that you hadn't expected to give dose.

In this case, the treatment site received between, a reduction between 20 and 31 percent of what the intended dose was. The

licensee did not calculate a dose to the unintended site. Some of the source paths extended beyond the planned end point and started on their turn path. And then some tissue protection was provided in the fluid-filled sleeve that provided some shielding in displacement, and the licensee said it was too complicated to provide dose to the unintended site.

Next slide. Now we've got four wrong sites. In the first one, we have a 5 centimeter site that received 500 centigray. The wrong software orientation was selected. This again was an Oncentra but for a different problem. In the treatment planning, you must chose if the treatment catheters are modeled from the tip or the connector end of the catheter. In this case, the licensee selected the tip end mode, which was incorrect. And they have corrective actions, provide additional training to personnel.

The next slide. In this case, they used a Capri applicator, and they inserted it into the patient's rectum instead of the vagina for the second of five fractions. It was interesting that they had to call on the radiologist to determine if they had put it in the wrong place. I think there would have been other indications.

The treatment site received a prescribed dose of, they claim that the treatment site received the prescribed dose during the second treatment. And then, as I indicated, the radiologist had to confirm that the rectum had been treated.

Next slide. In this particular case, the 5 centimeter site receiving 500 centigray should be deleted. That's immaterial for this case. There were two tandem treatments that were delivered as prescribed, but then one of the fractions, the incorrect tandem applicator length was put in as 115 instead of 131. And so it went to the wrong site.

Next slide. Okay. So in this particular case, the wrong site received 700 centigray. A wire was inserted in the length of the -- the transfer guide-to was 7 2 centimeters shorter than intended. They used a wire to make sure that the applicator was in the correct place. They pulled the wire out. There was a problem with the transfer guide-to. And so when they went to put the source in, it wouldn't fully insert and they didn't realize that until afterwards. So they're counseling the staff on the event.

The next slide. This was an equipment failure. The patient received a very low percentage of the intended dose. There were five separate interlocks that tripped in the first fraction. So the licensee stopped the procedure and sent the patient home, and then what they found was that there was fluid in the catheter that may have contaminated the source in the afterloader unit, and they did a decontamination and then they were sending the source and the catheters off to the manufacturer for evaluation.

The next slide. This is our Gamma Knife Model C. They were anticipating five shots. Three of them were delivered correctly. The couch retracted from the treatment physician due to clutch malfunction. The patient was released. They made the repairs, but the patient decided not to come back.

Next slide. So we've just gone through about 50 percent of the events. The other 50 percent are primarily yttrium-90 microspheres, and we did have one intervascular brachytherapy.

So on the next slide. For the intervascular brachytherapy, the prescribed dose was to be given for in-stent re-stenosis and in two

dwell positions. They were able to successfully give the first dwell position, but when they went to give the second, when they retracted the sources, the source got stuck in the train, in the source train, and they couldn't retract it into the afterloader. And they found out later that there was a deformation, 7.3 centimeters distal to the strain relief located outside the patient.

So there wasn't a treatment to the wrong treatment site, but the patient only got 50 percent of the dose they were expected to get. And they attributed it to compression of the catheter during a challenging advancement into the commonly torturous vessel, the left internal mammary artery.

Next slide. So now we get to the bulk of the medical events, the yttrium-90 microspheres. And the first group we'll look at are the Theraspheres. And you'll see some pretty complex reasons for medical events here.

We've got 15 events. Three are overdoses. We don't normally see overdoses. We have two wrong sites. We have four kinked catheters. That seems to be continuing. And we have one cracked catheter. We have a partial obstruction, two leaking connections, slow

infusion, and reflux to other loads.

Next slide. So in this particular case, we have an overdose. They used the wrong calibration date. There was a -- there are two dates. One is when you plan it and when you expect to give the material, and they used a much later calibration day than they should have. They used a dose calibrator that should have tipped them off. They did not question the results.

The written directive was not prepared, and it was not signed before the administration. And they had additional shunting to the lung with 2,000 centigrade to the lung and the intended was 500 centigrade. And they have looked at the patient about six months later, and they haven't seen clinically-significant complications.

And in this particular, the next overdose, they prescribed 35,000 centigrade. They administered 80,000 centigrade. They administered before the microspheres had decayed to the prescribed activity. The scheduling nurse used the pre-treatment plan instead of the final treatment plan, and the physician's pre-treatment calculations in timeout failed. So as I told you earlier in some of these things, many of the

corrective actions are a timeout. And in this particular case, and I have another one, the timeout failed to pick up the discrepancies.

Next slide. And to go into a little more detail on this particular one, the spreadsheet had calculated the patient dose and was modified. And when they checked the administrative vial for the calibrated activity date versus this is what they're going to do, they're going to do a spreadsheet to calculate the patient dose and they're going to modify that so that they look at the calibration activity versus the prescribed activity and the procedure date. And their timeout procedure was modified to confirm the proper activity prior to administration. So they're having to revise their timeout process.

Next slide. This is another overdose where they gave about twice as much as they needed. They considered it to be a human error in converting from gigabecquerels to millicuries, so their corrective action is to have a procedure modification, have written directive revisions, and software update to assist in the unit conversions.

Next slide. In this case, they were prescribed -- we're going to the wrong site. They

were prescribed 6,000. They administered 4,860 to the left lobe, and then they delivered 3,600 to the right lobe. They claimed they had challenging anatomy. They had a narrow window just distal to the vascular supplying the right lobe. And so they believed the microspheres refluxed back into the right lobe.

They verified catheter position because they knew they were in a very sensitive area that they could get back flow multiple times before the administration without any apparent complications they could see. But when they looked at their Bremsstrahlung images after the procedure, they realized that they had microspheres in both lobes. And they attributed it to movement of the catheter from some unnoticed patient movement, probably breathing, or angiographically undetected reflux caused by the difference in the flow dynamics of the microspheres, the contrasting agent, and the macro-aggregated albumin. So they are saying that we've got three different tests to see if we have it in the right place and where the back flow is going to be, and all of those tests have different parameters, so they may not be equivalent.

Next slide. We have a wrong site

again. Two separate segments of the right lobe were supposed to receive 25 millicuries to the small segment and 64 millicuries to the large segment. They discovered that they only ordered 10 millicuries for the large segment, so they had an error in ordering. And each dose needed a different calibration date. And then contrary to the vendor guidance, the licensee used one order sheet for the two doses with the one calibration date. So that led to problems in filling the order.

On the next slide, we'll see that this was a very complicated licensee. They had several hand-offs. There was radiation oncology that determined how much activity, and the radiation oncologist was an authorized user. They did it in consultation with the interventional radiology authorized user. The physicist calculated certain things. The interventional radiologist did the ordering. And then when it came back, they also switched people again, so everybody signed off on things, but it was just too complicated a handoff, so there were many, many places where there could be errors.

There was also inconsistency between

the written directive, the order, and the assay data. And none of that was identified prior to patient treatment.

Next slide. They prescribed roughly 47 millicuries to the left lobe, and they administered 46 to the right lobe. In this case, the interventional radiologist and the radiation oncologist authorized users, both of them are authorized users, signed off on the planned activity for the left lobe and via the left hepatic artery, and then the authorized user completed the written directive. But the interventional radiologist, when he put the catheter in, he put it into the right hepatic artery instead of the left hepatic artery and so delivered the dose to the right lobe.

Next slide. So this is one of the cases that I told you about where the operating room timeout for all parties is now going to be looked at more closely to confirm the procedure and the treatment that was administered. So they re-modified their written directive timeout procedures.

Okay. Next slide. Now we have four kinking ones. They prescribed 146 millicuries.

They administered 11. They had a slow injection. So this is a fairly routine activity and, through the slow injection, there was a dent in the outlook tubing from a pinch-clamp where they thought they had over-tightening of the Touhy-Borst Y adaptor, causing sedimentation of the microspheres in the delivery system.

They sent the catheter back to the manufacturer, and the manufacturer didn't observe any evidence of the Touhy fitting as being over-tight. And so they also saw there was a small mass of microspheres inside the dose vial, so they never got out of the dose vial, and within the outlet tubing. They did see locations with kinks, but they didn't see any fragments that came through.

The next slide. So I've got two cases here. One is prescribed 1,200, and they administered, 12,000, they administered 6,000. They had a kinked delivery catheter which prohibited the complete microsphere administration. In the second one, the residual, they prescribed 51 millicuries and they administered 39. There was residual activity remaining in the delivery device, and they could visualize a kink at the hub of the catheter.

Next slide. They prescribed 46 millicuries. They administered 20. They had two separate liver segments. They had two different procedures, and they got through the first one and they made a measurement and they decided everything was fine. But when they got to through second one, the acrylic jar, which is the waste area that they measure, contained 56 percent of the microspheres intended for the patient's second liver segment. So they looked at their protocols for dose preparation and the box construction, the dose administration, and all of those were followed. They found minor resistance during the flush of the stretched-out micro-catheter. They thought the micro-catheter had a kink and that they would be able to flush the contrast and saline through it, but the microspheres might still clog it even though they got saline and contrast flushed through the kink.

So next slide. We have a cracked catheter. In this case, they had two doses with a total of activity of 54 millicuries to the right and left lobes. They only administered 21. The first dose and the second administration through the radial artery of the left hand using the first

and second were both through the radial artery, and this is the first time we've had a micro-catheter identified as a Marksman. Most of the others either haven't been identified or have been identified by a different brand name.

So the post-radiation surveys, both in the microsphere vial, ended up with 5 mR per hour. The first one, the authorized user assumed that it was contamination from a cloth, but when he saw the second 5 mR per hour on the second procedure, he realized that they had two under-doses. So they did a visual inspection of the micro-catheter and it revealed a crack, and the crack was determined to be the cause of the event.

Next slide. In this one, we have a partial obstruction. So they were prescribing 47 millicuries, they administered 13. They believe the treatment went as planned. They didn't believe there were any issues with the flow before the administration. There was no increased resistance, and they could flush the line post-administration. But then they discovered when they surveyed the waste and were performing the dose assessment that less than half of the microspheres went into the patient.

Next slide. So this is a continuation of it. They thought there was a partial obstruction in the catheter where the line connecting the microsphere vial to the catheter and they thought the vascular was complicated and may have resulted in movement of the micro-catheter slightly forward from the initial placement. But they also identified they had an unusual amount of saline in the overflow vial, so that should have given them a hint that the procedure was not going as intended.

Next slide. Leaking catheter connection. So they were prescribing 11 millicuries and administering 8. And they had liquid leaking from the connector between the e-line, and they give different letters for the different lines within the microsphere delivery box so that they know which ones to connect to which area and what the flow is going to be. And so this particular e-line and the catheter that was going into the patient, there was a leak. They stopped the treatment. They started decontamination. They didn't think there was very much dose to the skin. And the incident was due to human error and the poor connection between the e-line and the

patient's catheter.

And on the next slide, so, once again, we have a leaking catheter. They were supposed to give 25 millicuries. They only gave about 9. And it occurred while connecting the infusion line from the microsphere vial to the micro-catheter. And the problem was that the physician simultaneously unclamped the administration line while trying to connect it to the micro-catheter. So the physician assumed that the leaking fluid was only saline and proceeded with the administration. They found out later that there was an area of contamination from the leaking catheter.

Next slide. Now I have one case of a slow injection rate. As I move into the SirSpheres, you'll see a lot of cases with a slow injection rate or slow activity, a low activity. So they prescribed 175 millicuries. They administered 43. They had a slow injection rate because they were worried about reflux into adjacent gastric artery that they could not embolize. And then they completed the administration, they did their flushes, they verified the digital dosimetry was reading zero, indicated all the microspheres had left the vial,

but the microspheres had collected in the catheter outside the patient.

Next slide. Another slow injection rate. Oh, this is continued. Okay. So they had external experts that they talked to, and they thought that a slow injection rate could result in an event like this, and the RSO identified the catheter backed up as another slow injection rate, on another slow injection rate administration.

So the next slide, we're moving into the SirSpheres. They had eight medical events, a label vial shield, not the vial; a low activity administration, three of those; and a high-activity clogging, one of those; and then they had other clogging issues with the needle and catheter and a kink.

So proceed to next slide. So they prescribed, and these are the low activity ones, and they prescribed only 2 millicuries to a small lesion and then 20 millicuries for a large lesion. And so they prepared two vials. They labeled each vial shield, but they didn't label the vials. So they provided the wrong vial for the wrong treatment. They provided the large activity for the small lesion and they didn't realize it until

they went to do the large lesion and only had a small activity.

So they're going to require timeouts. They're going to label both the vial and the vial shield. They're going to read the labels three times before administration.

Next slide. In this one, there's a low-activity administration where they're giving, and there are three of these cases where they're giving 6 millicuries to two segments, and they only administered 4.4. The activity was in the residual waste. Stasis wasn't reached, and there are procedure modifications.

There are going to be four modifications. There are going to be written directives adjusted to tighten up the dose to match 100 percent of prescribed dose. And they're committed to have the AMP physician -- this one didn't make any sense -- the AMP physician, I think that should have been "and physician," present to observe low-activity administrations.

So the next slide. They prescribed 5 millicuries. They administered 4. The cause of the event was the amount of, they believe the cause of the event was the amount of activity delivered,

that the relatively low prescribed dose made the residue look relatively large. And they are going to have another doctor supervise the remainder of the administrating doctor's cases. Now, this one made no sense because that should have already been part of the requirement for obtaining authorized user status, so it sounds, if they would have a physician in training, but he would have to be supervised for the rest of the tests anyway.

Next slide. Another low-activity one. They prescribed 4, and they administered 3. The radiation survey revealed that the residual activity of 1 millicurie remained in the treatment device. And they believe using small doses carried out with greater scrutiny and review.

Next slide. And now we've got a higher-activity clogging, and they prescribed 84 millicuries and they administered 59. They thought the tubing became clogged because the entire activity couldn't be administered, and they attributed it to the large dose of microspheres increasing the amount of microspheres in the system and clogging the micro-catheter.

Next slide. Clogged needle. They prescribed 32, and they administered 8 millicuries.

There was an occlusion of the vial delivery C needle due to clumping of the microspheres. They intended to return the apparatus to the manufacturer, but they discarded it, so it didn't get evaluated. And the manufacturer believed that educating the administrator on the microspheres and how to clear the clogged needle was all that was needed, so they provided training on reversing the valve for flush purposes to unclog it.

The next slide. So in this one, they were prescribing 12 millicuries. They administered 5. The AU and the interventional radiologist noticed strong resistance. The micro-catheter was pulled from the patient and a very small defect was observed. The cause of the microsphere blockage was a defect in the micro-catheter, and this one was reported to FDA under the MedWatch program.

Next slide. We have a kinked catheter, and they were prescribing 40 millicuries. They administered half of that, 21 millicuries. They think the patient inhaled deeply and created a kink in the catheter. The first three or four aliquots were delivered before the plunger met resistance. The kinked catheter was confirmed by PET/CT imaging of the administration set and vial.

Next slide. And we have completed all 43 of the medical events.

CHAIRMAN ALDERSON: Thank you, Dr. Howe, for that very complete report. I also want to thank you for giving us, as we had asked for it sometime ago, the year by trending of all these medical events. I think it's very useful to see that. I hope that will continue.

We are over time now, but I will point out that most of that isn't because of Dr. Howe's report. It's because we started late this morning. So are there additional questions for Dr. Howe before the next item, which will be taking a 15-minute break. Yes?

VICE CHAIRMAN ZANZONICO: Pat Zanzonico. There were two in the 35.400, these were the brachy implants, where one was attributed to patient anatomy and the other was, I guess, an under-dosing due to swelling and seed migration. Those kind of strike me as patient intervention. I mean, if everything were done correctly in terms of planning and delivery of the treatment and then subsequently happened within the patient beyond the control of the physician, of the treating team, that sort of strikes me more as patient

intervention, rather than a misadministration or a medical event rather.

DR. HOWE: Well, our current definition of patient intervention would not include those as patient intervention. But the new revision of Part 35 would probably do a different evaluation of the events, and they may or may not be a medical event based on the new criteria.

I would like to point out that we do get the NMED cases and we present them to you. But you'll actually get a thicker document that has each one of these in it. I have included an area in the back which are not medical events. They're the ones that came up when I searched NMED as medical events, but they don't meet the NRC criteria. And I've also included the Part 21 report for the Elekta software issue in there, too, for your information. Yes, Richard?

MR. GREEN: So there are 23 Y-90 microsphere events. One brand had 15 events, the other brand had 8. Do you attribute that to physician preference or market share, or is there a quality defect rate that you can attribute to one or the other?

DR. HOWE: No. We noticed that when

you have Y-90 medical events it almost seems as if the word gets out to one manufacturer that we're having issues with a certain area. So the next year, if we don't see very many for that manufacturer but we see more for the other, so they seem to trade back and forth. I'm not, I don't have information on the division between which manufacturer has which share of the market, but the devices are very different because of the small size of the Theraspheres and the larger size of the SirSpheres.

We are getting more complicated medical events on the Theraspheres. We're still seeing simple medical events for the Theraspheres that just don't seem to go away.

MR. BOLLOCK: This is Doug Bollock. I can add a little bit to that. So looking back over about 10 years, it does, as Donna said, it goes back and forth between the two. And we haven't seen a trend necessarily negative from one or the other or because of any design or any practice preference. We haven't seen anything with that when you look for ten years.

MR. OUHIB: Just a general comment here. Looking at these, you see that things are

repeating again and again. We go back through iodine-131 and you look at the microspheres, you'll look at other -- and it seemed like, obviously, we can report these, but if institutions or manufacturers are not learning and providing some action to actually avoid from repeating these, we're not doing the right job in my opinion.

So I guess I can probably do a survey, and I'm not really sure how many institutions have actually gone on the NRC website to look and learn from past events. We talk about learning from others' unfortunate scenario, but I'm not really sure if that's really happening.

So I guess I'm not sure who would be sort of the leader in this. Would it be the regulation, would it be the manufacturer or somebody else, to actually create a good summary that will reach every single institution. This is what has actually happened, and this is, which is more important, here's how you can actually avoid that scenario.

I mean, I look at the iodine-131 scenario, I remember looking at 10 - 12 years medical event, 2000 to 2012, and not seeing that happen. And I'm looking at it in 2017 and I'm

like, wait a minute, something is not right here, we've got to do something. You look at the microspheres, treating the wrong site, we've seen it before. It has been reported before.

So I think something has to be done in order to avoid that. And that's just my opinion.

DR. HOWE: And I think one of the things that you have to consider here is, one, we get very few medical events compared to all of the treatment. So most treatments appear to be going okay. The second thing is most of our medical events are caused by human error, people not paying attention. When we did the written directive requirements, at that point we called it the quality management rule back in 1992, we really attacked human error. We said you need to identify the patient, and you need to make sure that what you wrote down is what's ordered and that you need to make sure that what you ordered and what you wrote down is what's administered.

And then we put in 35.41, and we said you have to have a program to assure with high confidence that you've administered what you had in the written directive.

So we've tried to attack those

elements, and most of them are human error. But one of the things that we're doing with the revision to Part 35 is we're now making licensees determine if they have a medical event. And we think that will focus them more on, okay, I wrote this, I gave it, oh, now I've got to go back and look again and see if I gave them my intended and see if there are errors in it.

And then every once in a while we'll get a rash of these things, and if we get a rash of them we will send out an information notice, and the information notice goes to all of our NRC licensees and goes to the agreement states and they're asked to share them with their licensees. So we try to do that, but many of these cases are onsie-twosies over time. I mean, we can try to keep telling people pay attention.

CHAIRMAN ALDERSON: Dr. Ennis has a comment.

MEMBER ENNIS: Just following up on Zoubir's comment, I think he's right, there would be something advantageous about closing the loop a little bit more. So you alluded that the NRC, from time to time, will send out an information notice. Would it be worthwhile at the conclusion of your

kind of annual report that we come up with some or you come up with some kind of summary of the themes of the year or the themes of the last five years that would go out as information to everyone, look out for clogging tubing, cracking kind of things because we consistently see that and it's not going down. Look out for prostate bulb, penile bulb is not prostate, we've seen that repeatedly. If you could, maybe just alert people to the themes and what to look for or, you know, you've alluded to a theme, the checklist isn't the whole solution and, you know, you've got to do it right or whatever.

So perhaps that would help close the loop. You have a mechanism potentially and just let everyone know what you think the themes are for the last year or last few years as an alert.

MR. OUHIB: If I could just add to that, I think the most important thing, which is lacking sometimes in these reports, is corrective action. You look at the reports and it says corrective actions were implemented. Well, what are they? What was done to avoid that particular problem? It would be beneficial for people to learn from that also. I think that has a value.

DR. HOWE: And what we see on a lot of

corrective actions is retraining the staff. You retrain the staff, you retrain the staff, you retrain the staff. It doesn't seem to be effective. So we do see the same corrective actions over and over again.

Now we're seeing, because there's more focus everywhere in medicine about timeouts, we're seeing corrective action, timeout, timeout, timeout. And we're seeing that some of these timeouts, because the licensee has such a complicated system of passing off to the radiation oncologist to the interventional radiologist, and both of them are authorized users, and back and forth and back and forth.

MR. OUHIB: Yes, and I can think of these timeouts. There's a timeout pre-procedure, and there is a -- and it should be, and I hate to say it because this might sound redundant, but there's another final timeout source launching sort of like before. And I'll give an example of the case of the rectum, you know, vagina versus rectum. I'll give you the example of right versus left lobe. There is a final timeout, okay, we are treating this. It's sort of like just a site, per se. We are treating this. That would have been,

no, we're treating the left lobe, we're not doing the right lobe and, no, we're treating, you know, the vaginal cuff, not the rectum or whatever.

You know, it's like, it's sort of, you know, because in the preliminary timeout, this is the patient, this is case number two, this is fraction number whatever, this is this, this is this, and all of that. But there is, I mean, event thought they might mention the site prior to launching the source, someone might say wait a minute, you know, the only person who knows is the interventional cardiologist who is looking at the image and probably the radiation oncologist and can say, turn around and say wait a minute, I'm putting it in the right lobe, what are you talking about left lobe here, whatever. And then that, at least the source has not engaged yet. Just a thought.

CHAIRMAN ALDERSON: So as we are getting further behind time and because the next discussion after the break has to do with the safety culture of this issue, I would suggest that perhaps we defer those discussions which are part of the feedback until we get in there. Vasken has a brief comment.

MEMBER DILSIZIAN: Just one comment. I

think that, based on this discussion, I agree that there should be an educational component. And we did mention that part of the role of ACMUI and NRC is to scientific sessions. I would recommend that to have recommendations how to catch these and how to prevent it. I think that we are describing right now but what we're not doing is the next step. And I agree with Zoubir that we should probably take that --

CHAIRMAN ALDERSON: So we should bring that up during this next discussion. Are there any other items right now? Hearing none, thank you, Dr. Howe. We'll use that clock on the wall. We're supposed to have a 15-minute break, so we'll reconvene just prior, a couple of minutes prior to 11. Thank you.

(Whereupon, the above-entitled matter went off the record at 10:40 a.m. and resumed at 10:56 a.m.)

MR. BOLLOCK: Okay, so, I'm going to be going through our Staff Response to ACMUI Safety Culture Recommendations from your Subcommittee Report that we received last year.

I'm just going to quickly go through your recommendations from your report and then

provide our staff responses.

So, on September 11th of last year, ACMUI unanimously approved the ACMUI report, "Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture" which included the recommendations.

So, those recommendations included that the NRC establish a program allowing medical use licensees to evaluate medical events as described in 10 CFR 35.3045 and also in 10 CFR 35.1000 Licensing Guidance and 10 CFR 35.3047 with an approved patient safety program.

They also recommended the NRC licensees with an NRC approved patient safety program continue to report medical events as required with the following conditions.

That the NRC will not allow this event notification in the event notification report posted on its website, so not making it publically available.

But, the NRC will conduct -- will not conduct a reactive inspection on medical events unless the event results or will result in death, untended permanent harm or unintended significant

temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects.

The other condition was that medical use licensee will write a report available for the next NRC inspection describing the event, cause and corrective action taken.

And, the NRC will develop with ACMUI advice, new temporary inspection procedures for NRC review, licensee patient safety event reports and will evaluate with ACMUI advice the need to change enforcement manual procedures regarding medical events that support the tests of this program.

ACMUI also in the report also recommended the NRC should test out this program with a number of sites and duration to be determined at a later date, evaluate medical events reported or medical events reports with the ACMUI.

And, during this test period, the NRC with the advice of ACMUI should do the following.

Develop minimum criteria for patient safety program reviews, assess how this change to medical event reporting impacts the NRC's ability to protect patient health and to minimize dangers

to the patient's life and to evaluate the different types of patient safety programs and how lessons learned from the patient safety incident reviews are shared with the medical community.

The ACMUI report also recommended that after the completion of the test year, NRC should consider opening programs at NRC to all NRC medical use licensees who request approval of their patient safety program and to agree with States who request to implement the program with their medical licensees.

They also recommend the NRC define its -- redefine its perspective of patient safety to be different from occupational safety and from public safety.

It also recommended the NRC partner with the Department of Health and Human Services, specifically, the Agency of Healthcare and Research and Quality and the ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material.

And also, that the NRC -- they recommend the NRC update its medical use policy statement in 10 CFR Part 35 event reporting

regulations for patient safety programs to verify the active involvement of the licensee's patient safety program review of medical errors and reporting of reviews to the National Patient Safety database.

So, there's a lot in that report. Again, the report was unanimously endorsed by the ACMUI. So, it was a lot of us to swallow and we've -- so, it was a lot for us to look over and to consider.

And, in our considerations, our responses, we looked at and are these following this recommendation or are they meeting the purpose of medical event reporting and what limitations we would have or are there to conducting a pilot program utilizing the patient safety organizations.

And, what we'd have to do in changing our criteria for NRC reactive inspection.

So, the -- again, we're looking at the purpose of medical event reporting, which the Commission established in 1980 back when medical events were part of the administrations, but still applies with medical events today.

The purposes required or forced the NRC

to identify the causes in order to correct them and prevent their recurrence.

The Commission was able to notify other licensees of their possibility they could become -- they could make the same errors. So, looking at generic issues.

We feel we are -- staff is not sold, but the patient safety organizations presently meet that completely. And, again, I understand the recommendations are that we would have to look into that. But, right now, from the information we have, they don't fully meet our -- the purpose of the medical event reporting.

Our medical events allows the NRC to follow up on incidents in terms if other licensees might be making the same or similar mistakes or experiencing some of the same or similar challenges.

When we identify similarities in the problems reported from multiple facilities, we provide information that may help prevent additional incidents.

Some of the things that Donna Beth had mentioned through generic communications and other

-- and just the fact that our events are publically available, shared on the public website.

And, the information collected by the NRC is valuable in assessing trends and patterns, identify generic issues and generic concerns and recognize any inadequacies or unreliability of specific equipment or procedures.

This could -- this goes to -- it's a good segue into what Zoubir was talking about and Dr. Ennis was bringing up about looking for those hot topics for the year.

We actually do that on an annual basis. So, we, each year, we report to the Commission during an Agency Action Review meeting we call it, but in that meeting, we look at all materials events. But it is -- and the report from NMED.

There's so -- NMED runs the annual report which is publically available. And, as part of that, they do break it down to medical events and they look at trends for the past ten years and look -- and it will -- through that, we may be able to identify any specific trends or patterns that we may feel show a negative performance by licensees.

We also look for -- we will look at any

major negative performance by licensees and they report specifically to the Commission on that. That is rare for medical events, so I cannot recall when we've done a briefing of the Commission on that.

However, we do, if we feel that or have some indications that there may be a negative trend or some sort of pattern or trend, we can take a deeper dive and do a case study.

So, we ask the INL folks that control the NMED database to do a specific look at one type of either modality or specific type of material events or medical events.

And, in fact, we just did one this year on Y-90 looking at the tracks and trends and Yttrium-90 events.

And so, we do have a good idea of what has been happening over the past ten years, if we are seeing any significant issues with them.

And, to go to some of the points with the Yttrium-90 events, the number of events have stayed at relatively -- have been about the same, in the 20s over the past 10 years.

But, we do know that the rate of

incidents of the -- there is an increase in the use of Y-90, so the rate of incidents is very low and is actually slightly going down. And, that's using -- we do have some information directly from the manufacturers of microspheres to get that to kind of give us that other information.

So, we do know we have -- there's, again, the low rate of incidents. The low rate of incidents for all medical events is actually a factor in looking at the hot topics.

So, we do absolutely look for the hot topics. Unfortunately, when there's one, you know, we see something once one year and then maybe one another year or two later out of the 100,000, 150,000 cases where therapy -- for therapeutic uses. It's such a low rate of incidents, we may or may not share that in an information notice or take other actions. So, we do take that all into consideration.

And, that's one of the main factors is why you don't see information notices come out every few months or every couple of years from us necessarily, because just the low rate of incidents is a factor.

CHAIRMAN ALDERSON: So, do Dr. Ennis or Dr. Dilsizian wish to comment? I mean, your comments previously just a few minutes ago were to communicate more and get things back out to the user community in such a way that they were energized or educated by it.

And so, now, we're hearing that the low frequency of events is generally what has not, you know, has caused that not to really happen.

But, what do you think? Would your sort of communications still be useful even in a situation where the events are only occurring on a low, but repeated frequency?

MEMBER DILSIZIAN: Yes, I mean, it's, you know, I think there's been studies done on this at that human error factor of doing something complicated is about 3 percent.

And, if you look at our event rates, certainly less than 1 percent.

So, you could make the argument that we're doing great compared to others. But, the potential negative outcome of even a less than 1 percent event is great in medicine compared to some tasks that are, you could say, you know, working on

a car engine.

And so, I still think that, even though it's low, what the whole scientific community meetings that we attend, and if it's going to be a special session on NRC, for example, if I'm in the audience, besides learning what the rules and regulations and the changes, I would be really interested to know what kind of medical events occurred that's particular to, let's say, nuclear medicine or radiation oncology.

And, what are the root causes and how it could be prevented?

I think, to me, that would be something I would like to hear, even though it's a small percentage.

MR. BOLLOCK: Yes, and we appreciate that. And, we have listened to -- ACMUI was a big part of why we do post both Dr. Howe's reports on our public website and then Dr. Ennis's Subcommittee group when he does another review that we'll hear in the fall on the medical events.

We do post those -- the slides on the public website.

Also, going back to something that

Sophie had brought up in the opening comments about our discussion with the Agreement States and your recommendation to keep that open with getting that good information from them that's from the events and getting the root cause.

As Mr. Ouhib had also mentioned earlier, you know, we do, you know, we agree with you and we appreciate that feedback. And, we do agree that, you know, it takes the better information we have, the better we can respond to it and the better our communications out to the regulated community, I mean, this is, you know, the NRC 100 percent agrees there, you know, that is a good thing.

And, we'll continue to work to do that as best we can. So, we do appreciate those insights and the feedback from you all.

And, just because I say the incidents of rates are low doesn't mean we're not continuing to do this on an annual basis. We look for these, when we do see significant trends, we do take action.

I was actually just thinking from two years ago, the Committee recommended that we put

out an information notice on the kinking for the catheter kinking and tubing kinking for Y-90.

And, we did actually take a look at it two years ago and there wasn't necessarily a trend. However, you know, what, six events last year. So, maybe we need to take another look.

And so, we do continually do that. And so, we, you know, we are aligned and I think the NRC is in alignment with that and we do strive to pass on that good information where we can.

CHAIRMAN ALDERSON: You want to comment, Dr. Ennis?

MEMBER ENNIS: I want to just say, I think that even low rates, if they're steady and they're not declining, is a reason to try and further the education. And, whether that's presenting at annual meetings that you're invited to or whether it's sending out a special thing.

I do think it's great to publically boast Dr. Howe and ACMUI's alternating six month reports, but how many people actually are going to do -- going to look? You know, everyone's really busy.

But, a blast from NRC gets more

attention. So, it's just another way beyond just reporting it there to get it out.

And, you know, although the rates are low, we're seeing recurring themes over years and they're not going away as severe kind of a lot.

And so, I think there's room for additional education that would be helpful.

I also, you know, as we talked about before, I have some concerns about how accurate the rates exactly are and whether there's more events that are flying under the radar, so there may be more going on.

MR. BOLLOCK: Yes, we appreciate that. And, we recognize that's one of the -- kind of a theme of the ACMUI's report last fall on this.

We haven't seen that. We don't know what we don't know, and we recognize that we also can't take action on things we don't know.

And, you know, we have to, you know, between the NRC and the Agreement States, we do go out and inspect licensees periodically and ensure that they have a program and, you know, understand the regulations of the NRC or the state specific regulations and report as required.

CHAIRMAN ALDERSON: Mr. Ouhib?

MR. OUHIB: Yes, I guess in addition and, forgive me for not being a full member, I can't really make a motion here, but it would be desirable to have a group of people perhaps looking at these events and probably submit some sort of recommendation.

They're not rules, they're simply recommendations based on what we're seeing this year.

Here's what we recommend users to look at, pay attention, correct, whatever, if they have not done it already at their institution.

I think that would be beneficial sort of like because you're not just presenting the problem, you're presenting some ideas there how you can avoid these type things.

And then, welcome any others to actually submit to the group. Says, if you have any other recommendations, please send them to us and have somebody who is going to collect that information. And, we'll just revise that and put it out that at some point.

CHAIRMAN ALDERSON: Dr. Ennis has a

comment and then Sophie Holiday has a comment.

MEMBER ENNIS: I would just ask, I mean, the Subcommittee that I've been running to report on any events. We could take on an addition charge to give recommendations to NRC about things that we think might need some additional education if NRC would welcome and want that.

MR. BOLLOCK: Yes, absolutely, we would welcome that.

And, Sophie, if you have anything else to add?

MS. HOLIDAY: Yes, actually, this is exactly what I was planning to make the comment about with Zoubir's request, this is something that is totally within the scope for the Medical Event Subcommittee to do.

I know a lot of the membership has changed, but you may recall that, as a result of one of the -- of one year, the Medical Event Subcommittee had identified that there were a significant number of Yttrium-90 microspheres medical events that were reported.

So, as a result of that, a separate subcommittee was created to specifically review

those medical events.

So, absolutely, if the Subcommittee wants to review and make remarks about how they think there could be improvements or that they have noted, you know, some specific errors or trends with medical events, that is all within the discretion of the Subcommittee to do.

And, in fact, this is something that NRC and the greater medical community will benefit from. And, because you are the medical experts, the physicians and the physicists, this is something that you are doing every day and we do not have that specific knowledge and expertise, which is the whole crux of having this advisory committee.

So, this is who you can benefit and advise the NRC staff so that we can ultimately inform our policies, procedures and regulations for the medical use of byproduct materials.

CHAIRMAN ALDERSON: Yes, Dr. Howe?

DR. HOWE: I want to support what Sophie just said. Our original intent when I give the medical event report is to provide you with an organized view of how medical events occur during the year.

And, our hope is that when you do the fall medical event presentation, you will take it and maybe cut in a different direction and come up with what you think is important out of these events that I'm presenting to you.

I'm giving them to you by modality because they come in by date and it's very hard to see any trends that way. So, I do modality.

You may decide that, based on cutting across the modalities, it's time to give something about the time out, whether the time out appears effective or not based on what we're seeing in medical events.

But, that's our hope is that, in the fall meeting, your group will take something -- take what I presented to you in an organized fashion just by modality and come up with something that is from your perspective and different from what I've done.

CHAIRMAN ALDERSON: We have a comment from the audience here.

MS. TOMLINSON: Yes, sure, Cindy Tomlinson from ASTRO.

So, as you know, ASTRO and the AAPM sponsored the radiation oncology instant learning

system which is part of the PSO. So, on behalf of both organizations, we are happy to come in and talk to staff.

More specifically, I know we've done a couple of presentations on RO-ILS, but to come in and really talk about the nitty-gritty of PSOs and of what the information that is within RO-ILS and how maybe that could be beneficial to you.

So, feel free to reach out to me and we can make that happen.

MR. BOLLOCK: Thank you.

CHAIRMAN ALDERSON: I think that when you think about this idea, and I would -- I'd like to suggest, Ron, that your Subcommittee do take this up and bring it back for the fall agenda.

I hope, Zoubir, that you're on that Committee. I don't know the Committee, but if you're not, you're appointed.

(Laughter.)

CHAIRMAN ALDERSON: Because, and I'm going to use a generic term here, but, if you could figure out a good natured way, I mean, we're talking about safety culture which is a positive, affirmative culture based on the fact that some

things didn't go well.

A good natured educational way to get information out that would get to the user community, this is not easily solved when you think about -- but, of course, we've got the internet and we've got emails.

And so, it doesn't have to cost a lot. It can totally be an electronic communication. And, if it came out periodically, and just, and I wouldn't call it hot topics. I mean, it'll make for so many jokes, you know.

Anyway, but, you know, get it out so that the people can hear that, well, these events are uncommon, but when administering microspheres, a kinked catheter is a frequent recurrent -- frequently recurs as one of the problems.

And so, then, it's just got a couple of paragraphs and a little picture about, so, let's everyone pay attention, you know, to catheter safety.

I mean, you know, and that's all it is. You know, and it goes out twice a year or whenever it's appropriate in terms of the Committee.

I think that would be a big plus. It

would be educational. It also would impact in, I think, a positive way, the public's perception of the NRC as a regulator, you know, because it would be out there as a way to be involved with the community in a very positive way that's not in any way punitive.

I mean, here's information that we pulled our records together and we're providing this to you, you know, with the help of the ACMUI.

So, I think, Ron, if your Committee could help us get towards something like that, I think that would be a big plus.

Mr. Ouhib?

MR. OUHIB: I think as far as transmitting the information to the users, I don't see that as a big challenge. And, we have representatives here from different organizations.

The AAPM will be happy to actually put that in their newsletter and put the link there. The ASTRO will be happy and I'm sure the ABS will be more than happy to do that.

So, I think as far as getting that information to the people will be -- and we can label it in all three organizations as the patient

safety corner and that will be very catchy sort of like. And, it will be common to all three.

I think the work is going to come in getting -- and don't get me wrong, your data is extremely valuable, we just have not dug enough into it to make it very effective in changing what is actually happening.

CHAIRMAN ALDERSON: Yes, Dr. Suh?

MEMBER SUH: So, I also highly support trying to shift the culture from being somewhat of a more reactive culture to more of a proactive culture. And, I think that begins with education.

So, one suggestion I also would make is, these what I call best practices to build a higher reliability organization or culture is to also include the trainees as well.

So, within radiation oncology, we have the ARRO organization. And, I know as a trainee, they would really learn a lot. Because, here's some medical events that have occurred and here are best practices to avoid medical events.

And, I think if you hear it over and over, time outs are really essential. Time outs are really essential. This is how you can avoid X

percent of medical events from occurring by doing a proper time out, not doing a shortcut. Is it right? Is it left? Is it superior? Is it inferior?

And, if you keep going over that, it becomes part of a ritual habit for them rather than making a kind of a one off. Well, I'm going to skip this because I'm really busy right now.

And, I think it's very important to really have that.

And, also, getting on point, even though the number of medical events are really small, I think all of us, you know, from the public standpoint, from a professional standpoint, we really want to strive to be zero. Right?

So, it would be great someday, we have a report where the number of events were so small that it's a very short item on our agenda. Right? That should be the goal of the Committee.

I think a long-term is, I mean, it's a very aspirational goal, but it has to start with sharing this information.

And, I'll be very, you know, from my perspective, even though these events are listed on the NRC site, I would -- I'm not sure how many, just

to take radiation oncologists, for instance, how many actually look at that?

And so, maybe one way if you have a best practice that comes out from the ACMUI, that it goes to like say the chairs of various departments. Then, it's something you can disseminate to other faculty and to ASTRO and other organizations as well.

So, I think this is very important topic because, if you're really going to learn best practices, you have to share best practices. And, I think as a group, we've -- I think there's room to improve that.

CHAIRMAN ALDERSON: Yes, right, excellent statement.

Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: And, we've often cited around the table here, the excellent safety record of the airline industry. And, I think just about any industry practice aspires to their low rate of error where the error rate is -- where an error is pretty catastrophic, needless to say.

And, I think included in any communication, whether it's professional

organizations or whoever, needs to be an emphasis that the time outs and the item cited in the time out should be at every level of the care team from the most junior technologist up to the attending physician.

Because, items like vials mislabeled or activities not calibrated or not labeled properly, those can be identified often by the most junior people who carry a dose from Point A to Point B and so forth.

So, I think there should be an emphasis on the intervention, so to speak, by all members of the care team. And, we all know that hospitals, there's a hierarchy structure which sometimes inhibits that sort of thing.

And, I think especially in this case where we've noticed a lot of medical events related to what amount to clerical errors that that's sort of intervention we encourage as part of this communication.

CHAIRMAN ALDERSON: Good.

Well, I'll make one final comment. And so, I think we've agreed that Dr. Ennis's Medical Event Subcommittee will make recommendations

probably at the next meeting of the ACMUI. So, it should be on the agenda of things like content, style, how it's transmitted and so on to begin to get these ideas out into the user community.

So, thanks very much. Thank you, Dr. Ennis and all of you who made these excellent comments.

Are there any further comments on Mr. Bollock's report?

MR. BOLLOCK: Well, actually, I have a couple more points.

CHAIRMAN ALDERSON: Okay.

MR. BOLLOCK: That's just gets kind of the first part of the report.

(Laughter.)

MR. BOLLOCK: And, there's a --

CHAIRMAN ALDERSON: Carry on.

MR. BOLLOCK: Yes, I'll let Dr. Dilsizian have a say and then I can go through a couple more our --

MEMBER DILSIZIAN: I just had one comment. The bullet number three, I didn't -- I may have not heard you, what was your response whether you would consider --

MR. BOLLOCK: Yes, okay.

MEMBER DILSIZIAN: -- whether you would -- you're going to address it?

MR. BOLLOCK: I'll get to that, yes.

So, yes, so, getting to the next bullet, limitations to conducting the pilot program, the PSOs and some of the limitations with the PSO as being voluntary.

If we went to a system that was voluntary, even if we had approved it, if people decide to stop using it, right, reporting, because it is voluntary, that cuts out. I don't know that something that -- that's something that the NRC right now is not willing to accept.

There are a couple points, I know the Subcommittee had -- or the ACMUI's report to us spoke an anonymous reporting.

You know, we, right now, that would, as part of the regulations that what's got to be reported and what has to be reported in medical events in the regulations. So, it would take a regulation change.

But, we do -- I mean, we hear you, we appreciate and we understand the positives and

negatives to that.

And, the only other limitation for us in conducting the pilot besides some of things not, you know, being outside of the regulations, and unless we make changes to the regulations, we can't just pilot something that goes -- that's not a course of the regulations.

For us to review the PSOs, that is resource intensive for us and it's just the -- so, it's just a limiting factor for us. We would have to go out and verify it.

And, right now, we already have our structure in place and the Agreement States have their structure in place where they go out and do periodic inspections looking at their programs and report the medical events.

Now, we would have to go and approve, you know, the PSO at a site which is a different -- you know, it's a slightly different take.

And then, I do recognize that the ACMUI said that they would help us with developing that program, but it is resource intensive. So, that's just one of our limitations.

For both the PSOs, like the RO-ILS, for

instance, or an individual institution that has their own PSO program, I believe that was one of the recommendations was not just do one of the five, I think, approved PSOs, but if an institution has their own, if we approve it. So, it's, again, it's a different type of -- it's another type of inspection that we would have to conduct, we, as the NRC, would have to conduct.

So, there are some -- there are a lot of limitations to that.

And, to that, I think some of the discussion we just had earlier with things that are good that can help sharing information, things that we can do, maybe getting from your subcommittees reports on medical events, any themes, we'll call it, instead of hot topics, but that and sharing that using the listserv or helping to inform if we do decide to put out information notices to share the information.

You know, those are all very not resource intensive ways, I think. So, I, absolutely, I think those are great. Those are good things. It's always good to be able to find things that make a positive effect, you know, getting the

most bang for our buck.

And then, the last -- to the point, the change in criteria for NRC reaction inspections, so that is our Management Directive 8.10 is what determines our criteria for when to set up a reactive inspection at a medical facility.

For instance, if there is a medical event with an exposure over -- greater than 20 percent overdose to the patient, we -- the NRC will send out an inspection team within five days.

That Management Directive is up for a periodic change coming out next year. So, we'll start this year, we will start the process. So we will consider the ACMUI's comments and read the report and considerations for our update to that procedure and potentially making it in the changes.

CHAIRMAN ALDERSON: Excellent.

Questions or comments?

All right, seeing none, well, we have an action plan and so we look forward to hearing those reports in the fall and thank you for working with us on this important issue.

Okay? Well, that will take us to the next item on the agenda which is Sophie Holiday and

she's going to talk to us about the ACMUI reporting structure.

MS. HOLIDAY: I realize we are significantly over time, so I will try to make up for it in my presentation.

So, I am before you to give you your annual presentation to discuss the Committee's reporting structure, as I stated earlier this morning during my old business comments.

So, we will go over what the current reporting structure is. This will be your annual review, discuss how often we conduct our meetings and then open it up for a discussion amongst the Committee members.

So, this is a chart that looks very familiar to everyone on this Committee with the exception that I made a change to reflect our new division name, MSST. Previously, it was MSTR, and prior to that, it was MSSA. So, now we are MSST.

So, as this chart is trying to convey, the ACMUI along with MSEB, which is the Medical Safety and Events Assessment Branch, the branch that Doug is the Branch Chief for, we both report to the Division Director of MSST.

Again, that's the Division of Materials Safety, Security, States, and Trial Programs.

While our branch is responsible for doing the day to day operations of the ACMUI, more specifically, my responsibility, we both ultimately report to who is now Kevin Williams as the Acting Division Director.

But, we have the dotted lines on this chart to simply indicate that, while you may report directly to Kevin Williams or Dan Collins, whoever is the Director at the time, this does not preclude you from being able to reach out, communicate with, interact with, have drop-in meetings with- the Director for our office, Office of Nuclear Material Safety and Safeguards.

Our Executive of Operations, Victor McCree or to the Commission, we've had Dr. Alderson, I believe, had a drop-in with the Commission before. Dr. Thomadsen has had a drop-in with some of the Commissioners previously.

So, this is simply is saying that any member on the Committee has the ability to reach out to you, anyone in this management chain should you so wish to do so.

So, in September 2012, as was indicated on the old business chart, the ACMUI recommended to have this annual review of the reporting structure open indefinitely.

And so, the Subcommittee -- there was a subcommittee that was formed to -- for the ACMUI bylaws. And, Dr. Zanzonico presented to the Committee during May 2014 for the Committee to consider whether they want to continue reporting within the NMSS structure or if you wanted to report directly to the Commission, which is what our counterpart, the Advisory Committee for Reactor Safeguards, ACRS, does.

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

That's what was stated in May of 2014. But, of course, it was also requested that we

continue to have this annual reporting review.

This is the eighth review that we are conducting.

So, one of the items that were up for consideration is how often does the Committee meet? Whether that be meetings physically here at headquarters or via teleconferences.

So, as we are aware, we conduct two in-person meetings here at NRC headquarters a year. The spring meeting which takes place in either March or April and the fall meeting which takes place in either September or October.

Comparatively, ACRS meets here ten times a year and they report directly to the Commission. Subcommittee meetings also meet here, so they meet more frequently, which is a bit over burdensome for some of the members on the Committee, as was communicated in previous presentations for this topic.

We also hold approximately two to three teleconferences a year on an ad hoc basis. We've already had our two, last month on February 15th and, of course, March 1st.

I know we will likely have another one

later this summer once staff provides its review of training and experience requirements to the Committee for consideration.

So, again, the number of teleconferences varies from year to year, depending on the needs of the Committee and depending on the needs of staff and the Commission.

So, at this point, I would like to open it up for discussion to the Committee.

The questions for consideration are, do you still agree with the current reporting structure whereby you report to the NMSS management or would you rather report directly to the Commission?

Are you satisfied with the frequency of the meetings, that is the two in-person meetings here at headquarters with ad hoc teleconferences?

And, are there any other changes that you would like to see?

So, I turn it over to the Committee.

CHAIRMAN ALDERSON: Very good.

Okay, this -- these subjects are open for discussion.

Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: Pat Zanzonico.

So, when we originally considered this way back and initiated these annual reviews, Sophie put the fear of God in us that this -- what I think was sort of an appealing notion that we report directly to the Commission involved a lot more work and a lot more time on everyone's part.

As you said, our counterpart in the reactor business, the reactor side of the business, meets many more times per year.

And, I think that convinced everyone on the Committee at the time that what we were doing was perfectly adequate. Two face-to-face meetings a year, teleconferences as needed, plus, of course, emails and telephone calls and so forth, really was more than adequate to address our responsibilities.

And, you know, in the intervening years, I haven't felt anything has changed in that respect. That the frequency of face-to-face meetings, scheduling of Subcommittee -- of Committee and Subcommittee meetings as needed and electronic communications were perfectly adequate to meet our responsibilities.

So, personally, I don't see any need for any change in the reporting structure at this time.

MS. HOLIDAY: Thank you.

CHAIRMAN ALDERSON: Thank you, Dr. Zanzonico. Other comments from the ACMUI on that issue?

Seeing none, back to Ms. Holiday. I think that the Committee is happy with this structure. I think the fact that it has been reported back to us on an annual basis is useful. It reminds us all what it is and what the -- at least our predecessors, if it were true in that sense, that on this Committee voted to do, and Dr. Zanzonico's comment, you know, summarizes all that up.

Are there any issues related to any of this that people would like to bring forward at this time?

Yes, Ms. Weil?

MEMBER WEIL: Just another historical perspective. There was a time in the past when the Committee felt not inadequately supported by staff. And, that was the reason why we wanted to keep this live so that we could continue to reassess whether or not we were content and felt effective with the reporting structure.

I'm sure all of us agree that, I mean, we've had the best. So --

(Laughter.)

CHAIRMAN ALDERSON: Did you mean Sophie?

MEMBER WEIL: So, why would we change?

(Laughter.)

MS. HOLIDAY: Yes, I think we should clarify for the record that.

(Laughter.)

CHAIRMAN ALDERSON: Are there any other comments?

Well, hearing none, I think that this report is concluded. Thank you very much.

And I believe that our agenda for the morning is concluded ten minutes behind schedule and that's about where we started. So, thank you all for staying on that pseudo schedule.

The schedule shows us reconvening for the afternoon session at 1:00 p.m. by that clock, an hour and 20 minutes from now.

Are there any final comments before we adjourn for the morning?

Seeing none, I think we're adjourned for the morning.

(Whereupon, the above-entitled matter went off the record at 11:38 a.m. and resumed at 1:03 p.m.)

CHAIRMAN ALDERSON: So, with that, the next item on the agenda is Richard Green who is going to tell us about the worldwide supply and domestic production of Molybdenum-99.

MR. GREEN: Thank you, Dr. Alderson.

At the onset, I want to just provide the caveat here that this -- I apologize, this may be a simplistic presentation. I want to make sure it's discernable, digestible for everybody. We can get in the weeds and be real geeky later.

So, this is an update of a presentation I made in September of 2016. At that time, it was entitled, "The Worldwide Supply of Moly-99."

The change in the title recognizes the fact that, for the first time in 30 years, we have the domestic manufacturing of moly on U.S. soil.

So, moly-99 used in the U.S. the last 30 years has been produced solely through the fission of uranium-235. Uranium-235 is a very rare in its natural abundance. There's only 0.7 percent.

The degree of an enrichment is

important. Below 20 percent is referred to as LEU and above 20 percent is referred to as HEU, low-enriched and high-enriched uranium.

The production of fission moly-99 utilizes enriched uranium-235 targets either LEU or HEU targets but are placed in a neutron flux in a nuclear reactor that itself is fueled with enriched uranium-235 fuel, either LEU or HEU.

For the sake of clarity, I have to introduce a term, HSA, or high specific activity, moly-99. Before, we never had to concern ourselves with that term, but it's germane now because of the new generator system that's on the market today.

So, I'll be speaking specifically about high specific activity moly and low specific activity moly because they're made by different mechanisms.

In the fission production of moly-99, neutrons strike a uranium-235 target and split that uranium atom into pieces. Six percent of the result from fission fragments are moly-99.

There are current six reactors worldwide involved in the large-scale commercial manufacture of moly-99 that ship their irradiated targets to

four processors where they sort through the nuclear bits to isolate and purify the moly-99.

There are three commercial manufacturers of FDA approved high specific activity moly-99 generators utilizing fission moly in the U.S.

GE Healthcare's DRYTEC generator is made is Amersham, United Kingdom and shipped across the pond.

Lantheus Medical Imaging's TechneLite generator is made in North Billerica, Massachusetts.

And, Curium, you might know them by their old name, Mallinckrodt, their Technekow V4 generator is made is St. Louis, Missouri.

So, those are the three, I'll call them legacy manufacturers of moly-99 generators in the U.S. market.

All of these generator manufacturers use high specific activity moly-99 which is loaded onto a small alumina column and the sodium pertechnetate is released when the unit is eluded with normal saline.

Here are the current six reactors worldwide involved in the large-scare commercial manufacture of high specific activity fission moly-

99.

In the last few years, the Osiris reactor in France and the National Research Universal reactor in Canada, or the NRU, have ceased production of moly-99, leaving us with just these six reactors.

The LVR-15 in the Czech Republic and the MARIA reactor in Poland joined the supply network after the severe moly shortages the market suffered through 2009/2010. Glad to have them join the party.

The OPAL, Open Pool Australian Light-Water reactor is the youngest reactor on this list, operated by the Australian Nuclear Science and Technology organization, or ANSTO, in Sydney, Australia.

ANSTO has invested considerable resources in their Australian nuclear medicine project that will enable ANSTO to triple production of moly-99.

They have completed the construction phase and are in the process of completing their validation program.

The increased capacity will enable

Australia to meet their domestic demand as well as be able to supply up to 25 to 30 percent of the global high specific activity moly-99 demand.

It is of note, the progress made by the industry in converting from HEU to LEU. You see that column second from the right? Target type, as well as the one next to it, fuel type.

In converting from HEU to LEU for both fuel as well as targets.

Only the BR2 in Belgium and the LVR-15 in the Czech Republic remain to make that switch from high-enriched to low-enriched uranium.

In February of this year, Curium announced that they were supplying their customers exclusively with 100 percent low-enriched uranium moly-99 generators, making them the only North American provider to do so up to this point.

More on the American Medical Isotope Production Act, or AMIPA in a moment.

I've updated this slide to reflect the dedicated reactor processor relationships direct lines as well as the multiple reactor processor relationships that exist in some cases.

So, you can see that MARIA feeds

exclusively to the Curium processor in the Petten, Netherlands where the BR2 reactor could funnel its targets that have been irradiated to either Curium or IRE in Belgium.

Obviously, South Africa is insular, they feed their NTP processor and the OPAL reactor feeds their associated ANSTO processor in Australia.

On November 22nd last year, a halt to production at the NTP Radioisotopes facility, a subsidiary of the South African Nuclear Energy Corporation, or NESCA, was ordered, after it was discovered that procedural deviations related to a set of standard operating procedures were not followed.

There is concern about the -- I'm going blank -- we talked about it this morning, the -- it was not a radiological hazard, it was not a spill it was a concern about safety culture.

So, they said, wait, time out. You had an SOP, you weren't following the SOP, take a time out, figure it out and get back all on the same page. We need a safety culture.

So, NESCA, which is the nuclear license holder said that after they reported that matter to

their new national nuclear regulator that they received notification from the NNR to cease all operations in its active pharmaceutical ingredient production facility at NTP immediately. So, they called a time out.

NTP resumed production on February 21st at its facility after what was ultimately a three-month shutdown. Safety culture is important.

Unfortunately, this South African outage coincided with a scheduled maintenance period at the OPAL reactor in Australia.

Other reactors put into play their outage reserve capacity to increase the number of targets being irradiated.

Despite these efforts, there was a very rough week in December when supply fell significantly below demand.

Some manufacturers, depending on, you'll notice that if I go back a slide, that SAFARI is all LEU and OPAL is all LEU. And, they had contracted to provide one manufacturer on a certain day of the week enough LEU moly to produce a batch of all LEU generators.

As that manufacturer would say, the

order at Tuesday CAL, for example, you can buy an LEU generator and get additional benefit derived from CMS by getting an addition $10 co-pay payment on doses derived from LEU target material.

Well, both those reactors were down concurrently, that generator production cycle did not occur. Okay? So, it was a rough week in December.

But, for three months, South Africa was down.

Just yesterday, Curium informed the industry that the moly-99 activity for their Wednesday CAL, today, generator production was much lower than expected. This was due to one of their reactor partners and Curium can receive from BR2, HFR on MARIA, they were not specific in their announcement, was much lower than expected.

This was due to one of their reactor partners having a delayed startup after a scheduled maintenance cycle.

As a result of this issue, they had to reduce many of their customers' existing Wednesday calibrated generators today. So, there are already pharmacies today working with less than a full a

compliment of generators they would normally have.

After reviewing all of this not so pleasant news regarding legacy producers of fission moly-99, good news.

For the first time in 30 years, we now have a U.S. manufacturer able to supply moly-99 to the U.S. market.

This is occurring at the Missouri University Research Reactor, or MURR, and I will add that to the bottom of the list, in Columbia, Missouri.

This is a low specific activity moly-99 that I'll discuss in greater length in just a moment.

So, the top six reactor sources and processes are making HSA that can go into legacy generators. And this production source on the bottom starting at MURR feeding to their MURR factory in Columbia, Missouri where they fill source vessels is a low specific activity which requires an entirely different generator system to produce sodium pertechnetate.

So, let's talk briefly about the American Medical Isotope Production Act of 2009. It

was passed in 2009 and signed into law by President Obama, it has provided some degree of funding for at least two of the startup projects we'll be discussing today, to develop domestic production of moly-99.

It has also been the impetus behind that conversion from a use of highly enriched uranium to low-enriched uranium as a reactor fuel and as fission target material.

The goal is to reduce the potential for terroristic acts by taking and seizing HEU shipments.

This legislation effectively mandates the full conversion away from HEU as soon as possible and no later than January 2020, which is not that far away.

The moly-99 supply chain remains very complex and, as we have seen firsthand, in those last several months. And, we are still experiencing this fact even this week.

While the issues at NTP did not involve a radiological release or incident, it illustrates the fragility of the supply chain.

I know that the commercial radiopharmacy

industry has taken multiple measures to hedge their bets to ensure a consistent supply of moly-99 as best as possible.

This includes sourcing moly-99 charters from multiple charter manufacturers as well as operational measures such as frequent elutions and multiple deliveries to clinical sites.

You can't get any more joiners, you can just squeeze them harder and get more out of them, that works to an extent.

The association that imaging producers and equipment suppliers, or AIPES, A-I-P-E-S, coordinates a reactor maintenance schedules in an effort to ensure that when one reactor is down for scheduled maintenance, others are able to pick up the slack to the medical community and patients don't suffer.

The Nuclear Energy Agency, NEA, is a specialized agency within the organization of Economic Cooperation and Development, OECD, an intergovernmental organization of industrialized countries based in Paris, France.

OECD was working -- is working to understand the industry and assist in the conversion

to LEU fuel and targets as well as transition to the full cost recovery basis in these largely government operated subsidized research reactors.

For the industry to be viable and sustainable, we need to be on the same playing field and we can't have a low cost operator putting out HEU derived moly which would cost a lot less because 20 percent versus, you know, 90 percent enrichment, you're going to have five times as much waste using LEU versus HEU.

There is desirable reasons to go to LEU, but there are costs. And, those costs have to be uniform throughout the industry, otherwise, it's not going to work.

On February 8, 2018, the U.S. FDA approved the first domestically produced non-uranium based moly-99. The NorthStar RadioGenix™ system is a device designed as a totally closed system to contain, move and shield all of the moly-99 which is a mixture or radioactive moly-99, Tech-99m, and non-radioactive moly-98, or in the future, moly-100.

During a computer driven process of isolating technetium from moly before delivering technetium ^{99}M into an Elysium vial.

The moly in this system is not derived from the fission of uranium and requires a different system to isolate and concentrate the Tech ^{99}M than in the existing fission 99 legacy generator systems.

The NRC has promulgated licensing guidance for medical use licensees, medical use permittees and commercial nuclear pharmacies that was released in February of 2018 under the steady hand of Dr. Donna-Beth Howe.

The current production method for this moly-99 is through neutron capture of natural enriched moly-98. They take moly-98, make it into a solid metal target and put it down into their neutron flux at the MURR reactor where a neutron is added and it becomes moly-99.

But, a relative small number of atoms are converted from 98 to 99. Let's just say 2 percent. So, you're going to get a solution once you dissolve that target of radioactive moly-99, but it's not high specific activity, it's a lot of moly present, a very small percentage is radioactive moly-99.

So, in using natural occurring abundance moly-98, they can produce a source vessel, which is

what is -- what we could call a generator, a source vessel that is approximately 6 curies today.

Their next step to increase the activity in a single source vessel by using enriched moly-98. This will allow up to approximately 18 curies, or the top end DOT Type A quantity that could be shipped in the U.S., about 18 curies per source vessel.

NorthStar has built and qualified a source vessel filling facility near the MURR reactor.

As it was related to me, they intend to crawl, walk and then run. They intend to focus initially on units, placing units near the Missouri vicinity and adjoining states. They're not going to put one in Spokane to start with.

And, once they validate their mechanics and distribution and processing and retrieving abilities, they're going to go beyond that and enlarge their delivery radius.

I've heard from NorthStar, the longer term goal for them is to produce moly-99 without a reactor and that's by using a linear accelerator of proton bombardment of enriched moly-100.

Again, starting with stable moly by using a proton, knocking one neutron off or sorry, one proton off and making it moly-99 in that fashion.

NorthStar has stated that they have a goal to be able to provide 10 percent of all U.S. moly-99 demand in their first year after approval.

Now, I'm going to purposely go back a slide or two to give you the picture of the entire unit.

The moly-99 technetium liquid is received inside it's shielded radiation transport vessel, called a source vessel, I call it a keg. But, it looks about the size of a normal moly generator system, but it's liquid. It has approximately 30 milliliters of liquid potassium molybdate.

It is placed in one of these four doors on the middle row of that generator system. There's two on the far left, two on the far right. There's one in the middle which has a unique purpose.

The vessel is connected to tubes that move the tech moly liquid by computer driven valves and a syringe pump located behind that service bay

door. The service bay door is the top largest door in the center of the unit.

The moly tech is moved by the primary separation cartridge, cabinet where various chemical solutions located handing on top of the unit. You see in the IV bag type device which will react with that moly tech solution and column to make that moly pass through the column, but the technetium is filtered and retained on the column.

So, in a computerized mechanical process, it's going to pump 5 mils from the source vessel through that filtration column, moly goes through, tech gets captured.

You get the next 5 mils, repeat, next 5 mils, repeat until all 30 mils have been pushed through that exchange column, that filtration process.

And then, upon command, it will elute that technetium through the chemical agents to that far right door on the right hand side on the top which is where the technetium will be delivered in a tungsten shielded vial, much like we do today.

So, additional chemical solutions are used to wash the technetium from the first column

and then through a second column into that product cabinet into the collection vial.

The various chemical washes are pumped through valves to one of those two discard material containers. Those two doors at the very bottom of the unit in the center are to contain waste liquids used in generating during the elution process.

At the end of the process, the moly is returned back to that source vessel from which it came. So, they can have four generators or four source vessels in those bays and you can elute one at a time by pushing liquid through that column and extracting the technetium.

So, because we're working with low specific activity, it's an entirely different animal than the high specific activity legacy generators that we have today.

But, we're excited to have a new source of moly-99. More moly is good, moly from non-HEU is good and I would argue that domestically made moly is good as well. Glad to have it.

There's an example of a source vessel in this photograph here.

Once the moly-99 is no longer usable, or

reaches its expiration date, is returned to the source transport vessel to be returned to the manufacturer.

So, that was approved in February. Another company that you may have heard of in the January 15th of 2018, an article appeared in The New York Times entitled, "Inside the Global Relay Race to Deliver Moly-99."

This article is primarily focused on another startup company, SHINE Medical Technologies. SHINE is pursuing the manufacture of moly-99 via the neutron bombardment of a liquid uranium salt solution.

SHINE has completed the construction of what they call Building 1 in Janesville, Wisconsin. They will house their first integrated accelerator production system.

Moly-99 produced via this method that's being pursued by SHINE has been successfully made, loaded into a GE DRYTEC generator and successfully eluded and made commercially manufactured drug kits today. So, we know this technology works.

But, we should look for this system to become operational in a few years, probably 2020 or

beyond. So, that's a future project.

I pestered my boss. He went to Paris, France, poor guy, and attended the OECD meeting earlier this year and he brought back this chart for me to show you today.

This is from the recent OECD meeting that was held in Paris February 19th through the 22nd. It shows current fission produced moly-99 production and projected demand.

So, the red line on the bottom is the demand growth with no outage reserve capacity. This is just standard targets that normally put in the reactor.

Again, many reactors have what's called outage reserve capacity so they have normally eight slots they can occupy with targets. But, they've rented space and they can put in 12 if they need to.

So, the red line is that standard demand curve.

The green line is the demand growth with that outage reserve capacity so they could very easily bump up production to that level.

The blue line is the total of radiation capacity and the yellowish line is the total

processing capacity.

So, I don't want to paint a discouraging picture, I think it's a promising picture. We have moly.

Yes, we have two less producers, large Canadian reactor is gone off the map and a French reactor has gone off the map. But, they were each, you know, older than I am. And, you know, bad knees and bad hips, reactors get it, too.

But, we've got coordination, we've got collaboration, we've got scheduling coordinations so that we don't have two reactors hopefully, knock on wood, down at the same time as we did for three months in December, January and February.

And, then now, most of all, we have a domestic manufacturer and others trying to get into the game.

So, that's a status report on where we stand today with moly. Today, we're still suffering, literally, today we're suffering, but we're doing the best we can within the resources.

Any questions?

Yes, Doctor?

VICE CHAIRMAN ZANZONICO: That was

terrific update.

I just have a technical question. So, the fact that you're chemically isolating the tech, the fact that it's being made from low specific activity doesn't have any adverse effect of kit production or any such thing as that?

MR. GREEN: In simplistic form, tech is tech is tech.

VICE CHAIRMAN ZANZONICO: Right.

MR. GREEN: It's a different way to get there. And, actually, they were rather ingenious. They -- very early on in the '70s, there was a commercial manufactured low specific activity generator, I think that was put out by E. R. Squibb & Sons which today we would call BROCO.

And so, they filed an ANDA with this unit. They didn't have to forge a new path and file an NDA. So, they took an easier route to the approval process.

So, they've got an FDA approved product. Today, they can make a 6 curie source vessel. Once they amend applications with the FDA to swap out natural enriched to natural abundance to enriched moly-98, then they can get an 18 curie source

vessel. And, that still uses a reactor in MURR which I think is a very utilitarian high uptime reactor that we have access to here in America.

But, once they have an accelerated production system in their own plant in Beloit, Wisconsin, then they'll be able to produce it right there.

It's my understanding that they'll keep both systems viable. You don't want to put all your eggs in one basket. But they'll have multiple ways to make moly.

VICE CHAIRMAN ZANZONICO: Another question.

So, would that, within that base production, do you then what energy protons you need for that? Just in terms of the sort of the viability of that?

It becomes much more expensive as the energies grow up.

MR. GREEN: Well, I'll be a smart aleck and tell you, I'm not a business, but I work with several. I'd have to ask them about the energy levels required.

I know it's not horribly exorbitant. In

their case, they're just knocking a proton off of the 100 atom to make it 99.

The SHINE process is different because they're actually making it from the accelerator hitting a target material, making a neutron flux which then causes fission in a liquid target uranium solution that they're able to tap and extract the moly and then put the material back in to use again.

VICE CHAIRMAN ZANZONICO: One last question.

So, I mean, what they're envisioning is that these systems would just go into regional commercial radiopharmacies. These would not be hospital based systems?

MR. GREEN: Well, the NRC guidance is for both clinical hospital sites and commercial radiopharmacies, if they elect to get one.

Now, it is a rather large footprint. I believe it's approximately five feet. I think it weighs 3,000 pounds. So, it's -- if you're a small clinic, small site, I don't think you would likely be in the market.

But, if you had the capacity to have four generators in one system, and you loop

generator A and then generator B and C and D, then it may be more applicable to a commercial radiopharmacy setting.

CHAIRMAN ALDERSON: I'd like to ask about -- this is Dr. Alderson -- I'd like to ask about -- maybe I should say I'd like to be reassured further about this low specific activity idea.

So, I'm going to reflect my ancient, you know, legacy in the field to say that I remember, you know, when, you know, we would get our tech generator made the old-fashioned way on Monday, you know, and it was high specific, it was high, you know, we could get out small doses.

But, by Wednesday, it wasn't so good because the activity was declining and we had to get a second generator delivered, you know, later. This was at Milacron Institute which is, you know, was a busy, and then, even a busy facility.

So, we had to get a second generator delivered so we could get to higher specific activity eluates.

So, we had a problem clinically. We felt that with low specific activity eluates.

Now, maybe it's just a matter of what

low really means here, but why shouldn't be worried about that?

MR. GREEN: Well, in your case, as you're describing, you were using a fission generator, where all the atoms of moly were radioactive atoms of moly.

And, you could change the elution volume to some degree to change the concentration.

CHAIRMAN ALDERSON: Right.

MR. GREEN: But, as always, high specific activity moly, because there was no stable moly in that column, the alumina column had nothing but radioactive moly because it was broken pieces of uranium, the bits they sorted out through the moly pieces and put them on a column for you.

In this case, they take stable moly and make some of them radioactive moly-99 and that's all dissolved with acid into a liquid solution of potassium molybdate in 3 milliliters and you're pushing that mechanically through this filtration process and extracting the tech -- holding the tech, moly goes through, the tech is held.

And, once you've pushed all the moly liquid through, then you chemically tell the

computer system, okay, now, elute -- rinse all the technetium off into my elution vial.

So, it's still going to be nothing but tech-99M and tech 99.

CHAIRMAN ALDERSON: I see.

MR. GREEN: But, it's --

CHAIRMAN ALDERSON: So, what you elute is high specific activity --

MR. GREEN: Correct.

CHAIRMAN ALDERSON: -- you know what's in there is low --

(Simultaneous speaking.)

MR. GREEN: The moly was low but the tech is high.

CHAIRMAN ALDERSON: I got you, okay.

MR. GREEN: It's quite an ingenious system. And, it's -- they've had a long road to hoe but I'm very pleased that they've made it thanks to the FDA.

CHAIRMAN ALDERSON: Dr. Palestro?

MEMBER PALESTRO: A question, you may have mentioned it and I didn't catch it, but what is the cost differential for producing technetium-99M through the conventional generators that we have now

versus NorthStar? If that data is available either in terms of millicurie or curie or however you would compare it.

MR. GREEN: I'm a clinical geek, I don't have financial numbers. I don't do math. My dad was a CPA, not me.

But, I can give you a couple guardrails. We were enjoying 30-plus years of high specific activity fission moly from cheap HEU fuel reactors using HEU targets.

Well, now, we're going to be using LEU targets.

So, to get the same number of curies, I've got to use five times as many targets because it's 20 percent and it may have been, say it was a 100 percent. So, now, it's going to have a lot -- five times as much radioactive waste as much processing as my storage.

So, there's a lot more bits to sort through to get them out of moly that I used to get in one target. That cost has to come up.

The other thing is, they're going to have to say, hey, Belgium government or Australian government or South African government, you can't

subsidize these. I know these reactors are not solely there for making moly, they do other things. They do moly on the side.

Well, they need to have full cost recovery so they're not propped up and supported.

So, tech is not going to be cheap. Now, SHINE and NorthStar who are not using fission to get moly will tell you that they think theirs will be economically viable because you don't have all of that waste stream.

I'm not sorting through the bits to get 6 percent moly and 94 percent waste which has half-lives of who knows how long.

So, I don't know what the true economics are, you know, per curie, but there's arguments that the legacy systems are going to go up because the LEU and there's more waste.

And, perhaps these other innovators may have a cost advantage, I don't know yet. But, in my mind, one moly is good, non-HEU is good, and I'm not opposed to domestically made moly either.

CHAIRMAN ALDERSON: Yes, Ron?

MEMBER ENNIS: Just more for my education. So, the switch to low from a safety

perspective is just what the community thinks, like is that -- is it really a lot safer? Like, that would be number one.

And then, number two, among the now the different technologies that are available, just can you share what like what the pros and cons are to them, particularly from a safety perspective since that's what we're mostly interested in hearing?

But, also, just a little more broadly?

MR. GREEN: Well, I think the document that Donna-Beth Howe and her team has prepared that was released last month, I mean, in the legacy system, the moly is static. It's on a fixed alumina column and I push water past it.

In this system, the liquid -- low specific activity gets a liquid moly solution and I'm pushing it around.

And so, there are requirements -- there are certain doors on that locked cabinetry you don't open, you know, unless NorthStar's on the phone telling you what to do or they're physically present.

You have to -- may have to put radiation signage on all four sides because when it's moving

and processing moly, you've got a radiation flux that's here for 10 minutes that won't be there 10 minutes from now. So, it's not static.

Your term, you said was safety. I don't think any of these are unsafe. They're just different. I've used both systems, both produce technetium and Dr. Alderson's question, technetium is technetium, glad to have it.

CHAIRMAN ALDERSON: But, the safety can be looked at from different perspectives when you -- yes, the generator's safe for the patients, but the reason that they want it to be low-enriched uranium is because they don't want other people to get their hands on the high-enriched uranium to pirate it.

And, that's where that safety comes in.

MR. GREEN: You've got an operator making a dirty bomb.

CHAIRMAN ALDERSON: Right, exactly.

MR. GREEN: Yes.

CHAIRMAN ALDERSON: That's where another aspect of the safety that I think the NRC will be concerned by.

MR. GREEN: Global threat reduction at issue.

CHAIRMAN ALDERSON: Any -- yes, question from Dr. Daibes?

DR. DAIBES: Mr. Green, do you see -- sorry, Said Daibes.

Do you see NorthStar supplying the needed market, being something that is available now? Do you see this as --

MR. GREEN: I think they envision themselves to start with because they're working with natural enrichment moly and they can only make a 6 curie source vessel at the moment.

Until they get an amended application with the FDA to use enriched moly-98, they are limited to roughly 6 curies per source vessel, I understand.

Today, in a legacy system, I can buy an 18 curie generator. Okay? So, they're not a one for one swap. But, they're a producer so it may be in the mix. It may be 10, 15, 20 percent of the technetium consumed, it's not going to, I think, replace all units in all facilities.

But, we had three manufacturers, now we have four. I've got to look at my fingers when I count.

CHAIRMAN ALDERSON: Yes, other questions?

DR. DAIBES: Just a general comment. I mean, considering that there was a crisis at one point and there is potential crises down the road, is there anything in parallel as a possible technology to actually overcome this crisis down the road that you know of?

MR. GREEN: Well, I think they've done a lot of things. I mean, we were -- it's not that we were naive, we were unprepared in 2009/2010. Community reactors got holes in the stainless steel vessel, it's leaking all over the place. There's problems with the cement, tubings in Holland.

The two biggest reactors that supplied roughly 6 percent of the moly in the world went down for almost a year. That was rough.

But, back then, we didn't have any coordination. We didn't have France tell Australia, hey, I'm going down for three weeks here to refuel my machine. You stay up while I'm down. Now, we have that coordination.

Now, they've qualified additional target slots. So, rather than having just 8 targets being

bombarded for a 6-day curie production cycle, they've rented the space and now they've got outage reserve capacity, they can take that 8 and make it 12.

If you tell me, I'm going to be out doing a maintenance cycle, I can pick up the slack. The other generator -- the manufacturer can pick up the slack by using those other slots and creating more targets.

So, we've got the coordination, we've got the outage reserve capacity. We've got more alternatives today than we had. We were unprepared in '09 and '10. We're better prepared.

DR. DAIBES: But, you always have the unknown, though.

MR. GREEN: Who knew, I mean the article in The New York Times said it was a baboon that got into the reactor hull. I don't know if that's true or not.

(Laughter.)

MR. GREEN: We can discuss their validity as journalistic source. But, safety culture, shutting down, not a spill, not a release, not an exposure, safety culture issue shutting down

for three months. And there was -- the reactor was not shutdown, it was the processor that sorts through the bits.

And so, and then, it happened to be that the OPAL reactor was down for maintenance in that cycle. So, that really added the additional pain.

CHAIRMAN ALDERSON: So, Richard, NorthStar is up now?

MR. GREEN: Their drug is FDA approved.

CHAIRMAN ALDERSON: FDA approved? It's up there? I meant, they're selling the product now?

MR. GREEN: We have a representative from the state of Wisconsin Agreement State who can give us direct information on their license status.

MS. SHOBER: Yes, Wisconsin does have the -- we have an application in for the distribution license for that generator product.

The distribution license has not been issued yet. We are still waiting, coordinating with NRC on the safety evaluation report for the generator.

CHAIRMAN ALDERSON: I see. So, pending local approval, it's not really being distributed yet?

MR. GREEN: Not yet.

MS. SHOBER: Better not be.

(Laughter,)

MR. GREEN: We hope so.

MS. SHOBER: Yes, I mean, we're expecting within the next several weeks or --

CHAIRMAN ALDERSON: Several weeks?

MS. SHOBER: -- you know, short relatively short-term.

CHAIRMAN ALDERSON: And then, SHINE is about two years?

MR. GREEN: Two or beyond.

CHAIRMAN ALDERSON: Yes, all right.

Well, Wisconsin's going to be the important place to be.

MS. SHOBER: Well, SHINE has an NRC license for their production facility. And, we're just licensing their demonstration site.

CHAIRMAN ALDERSON: Oh, okay, all right, very good.

MR. GREEN: But, who knew? Southern Wisconsin.

MS. SHOBER: The place to be.

CHAIRMAN ALDERSON: Any other questions

for Richard?

Seeing none, thank you, thank you. Excellent report bringing us up to date on this future issue.

Okay, medical -- the next report is back to Doug Bollock again on the medical projects on the horizon.

MR. BOLLOCK: Good afternoon.

I'm just going to give a quick overview of some of the major projects that the medical team is working on. And, I'm Doug Bollock, I'm the Chief of the Medical Safety Events Assessment Group.

All right, so, just a couple of major projects that the medical team is working on right now.

As you're all aware, Part 35 rule was approved by the Commission last year. We are awaiting OMB's final review for impact before that rule to be published for the near future.

We've reached out to find out an estimated time when we'll get it back. Have not heard back yet on that. But we are engaged and hoping that comes out shortly.

But, with that rule change, there are a

lot of other things that have to happen.

So, NUREG-1556 Volumes 9 and 13 have to be updated to reflect the changes in the rule. And, Donna-Beth Howe is working with the NUREG-1556 working group to incorporate those.

Also, besides that, we are working on the other NUREG-1556 Volume 9 and 13 updates. Katie Tapp is working with -- Dr. Tapp is working on that along with a working group including other NRC employees representation.

Germanium Gallium generators, as we know, last year, I guess two years ago now, we approved the 35.1000 licensing guidance for the Eckert Ziegler generators.

But, what we are working on, Dr. Daibes is working on 35.1000 guidance for current and future generators. So, a more generic licensing guidance so we don't have to update it every time a new generator comes out. We just have one that covers all the generators. We think it's -- we have a path in sight to be able to do that. So, we're working on that right now.

Physical presence requirements for Leksell Perfexion™ and Icon™, y'all had -- ACMUI had

a teleconference last month on this. And, Sophie Holiday and the Agreement State working group are working on changes to 35.1000 guidance and considering the comments from the ACMUI in their determinations for any changes there.

Yttrium-90 microspheres, the topic of the day today, another -- as Katie Tapp indicated earlier, there were -- we put out a Federal Register Notice for public comments on the 35.1000 guidance. So, we're Revision 10 to the 35.1000 guidance on the Yttrium-90 microspheres went out for public comment. The first time we've ever done that with 35.1000 guidance.

And, we understand and recognize it's not the same as going through rulemaking in that full, you know, all the public input from that. However, it's a step and we believe it's a step in the right direction to get some further insights from the users and the public to inform us on our next revision.

And, so, we've received all of our comments over 100 comments were received by the public. Some of them were, you know, we agree with this standard letter, but so, I think it was 134

comments is the last number I had heard and we're still in processing those comments as that just closed a couple weeks ago.

And, once we get all the comments, Katie will lead the Agreement State Working Group on going through those comments and incorporating, or potentially incorporate, anything into the next revision to Y-90 microspheres.

Patient release, so, as you were all informed this morning, we set the -- the staff sent a SECY paper to the Commission on patient release last month, or actually, the end of January.

However, our work is not done. We are going to update our guidance on patient release which is Reg Guide 839.

As I'm sure many of you all are aware, NUREG-1556 Volume 9 Appendix U also provides guidance.

What we're doing now is the Volume 9 Appendix U will refer to the Reg Guide. So, we will just work on changing that one document and not have dual documents with potentially different information if we update them in the future. So, we will just have the Reg Guide and be updating that.

And, some of the things that will be going into the updates include the best practices and other information that we provided -- the NRC provided in an information notice last year, May of last year, that the ACMUI reviewed and gave us many, many good comments.

We've actually seen a lot of kudos for that information notice. And, a lot of that will be included in the Reg Guide update.

And, last, but not least, training experience paper. So, the staff was -- when the Commission approved the Part 35 final rule, they also in their SRM with the approval directed the staff to evaluate training experience as we discussed in the teleconference last week.

So, we owe the Commission our staff's evaluation on our training experience requirements specifically for 35.300 at the end of August of this year.

So, we will be -- staff will be quickly getting our recommendations thoughts on paper and sharing it with the ACMUI later this spring.

So, that's some of the major projects that the NRC is working on.

We also -- we are reviewing potential rulemaking that we received from the organization of Agreement States to add isotopes to the 10 CFR Appendix -- or 10 CFR Part 35 -- or Part 30 Appendix B table, this is -- if y'all remember, this is the table that was discussed many times because it did not have germanium-69 in the table.

And, that's why we need an exemption for the germanium gallium generators because the use of those generators automatically kicked into requiring a decommissioning funding plan.

So, there are a couple of isotopes that were recommended by the Organization of Agreement States.

Also, the staff put out a *Federal Register* Notice soliciting for other isotopes. I don't think we received many, so I don't know if there are any others outside of what the original petition had.

PARTICIPANT: Roughly 10.

MR. BOLLOCK: Ten? Okay, so there's 10 additional isotopes. So, the NRC is reviewing that and Said is part of the petition review group for that. So, that's another major project that we're

working on.

And, as Dr. O'Hara's well aware, we are also working with the FDA in updating our FDA NRC Memorandum of Understanding. And, that's just how we are able to communicate and share information between the two agencies.

And, those are all the major work. That doesn't count all the day to day answering questions that we receive from our regions, from the states and from the general public on our regulations, our practices and everything across the board.

There's a lot of work for a small group. If you look around, there's only a couple people sitting on the edges here. And, in fact, we actually had to supplement our staff this year in order to get the SECY papers that we needed to write for the training experience and also for emergent technologies.

I was able to add for this year, Irene Wu to the medical team.

So, it's a lot of work. We've got a very dedicated staff, thankfully, keeping us very busy.

And, you -- as the ACMUI, if you're not

aware of what's going on, you will be. There will be multiple opportunities for us to share information with you and seek your guidance on many of these projects.

Any questions?

CHAIRMAN ALDERSON: Okay, yes, Laura Weil?

MEMBER WEIL: So, when is your paper to the Commission on training and experience going to be finished?

MR. BOLLOCK: August, the end of August.

MEMBER WEIL: And, how does that mesh with the work of our Subcommittee?

MR. BOLLOCK: So, it's -- it can go in parallel. Now, we -- the staff was directed to provide our staff evaluation to the Commission. So, before any actions can happen, you know, before anything -- any actual changes would occur, there is a lot of other steps to get to that point.

We would seek a lot of other input to do that. So, this is just one part of that and one step in that process. But, it works in parallel with -- but we, as staff, we have to respond to the Commission.

MS. HOLIDAY: Dr. Alderson? I'm sorry, this is Sophie.

If I could maybe add a little bit of information, I think what Ms. Weil is trying to ask or ascertain is, is this going to expedite the review that the Subcommittee is performing?

And, I think, as we explained during the teleconference last week, similar to when we have rulemaking changes or NUREG-1556 or other guidance documents, staff will be providing its paper, its draft paper to the Committee for their review and their comment.

This does not necessarily mean that the Subcommittee's overall review of training experience comes to an end.

MR. BOLLOCK: Right, nor does that mean that you have to -- we'll ask you to review our evaluation. But, what your Subcommittee is working on for any recommendations directly from the Subcommittee does not -- that doesn't affect the time line there. You can work that in parallel.

CHAIRMAN ALDERSON: Question from Dr. Palestro on that?

MEMBER PALESTRO: Yes, I'm sorry, I

didn't follow what you just said.

MR. BOLLOCK: Our paper doesn't affect the work that you're doing.

MEMBER PALESTRO: Well, the way you're describing it sounds to me almost like it's duplication of effort. In other words, why would we both be working on the same topic separately?

I understand if you're going to prepare a draft of a paper or a proposal for the Subcommittee to review and to critique and to make suggestions or vice versa, it doesn't really make any difference to me.

But, for the two groups to be working on the same topic independently, I'm not sure that that works very well, especially when you have deadlines to meet, unless I'm just not understanding what you're going to do.

MR. BOLLOCK: We have our deadline -- right, we have our deadline and what we owe, you know, the paper. So, we can discuss further the offline or I'll say it right here.

Really, there's not -- if you feel it's duplicative, I mean there is a sense that it is duplicative, but we understand that. We do want to

seek the ACMUI's Subcommittee view.

If you're doing other outreach and things that we don't have access to, we don't work in clinical settings, we don't have the same connections to -- that you necessarily have.

We do it through you in a lot of cases, right, but we don't necessarily have that. We just -- what we owe the Commission is our staff evaluation, so it's the staff's opinion on what we are directed to do.

So, we can work that in parallel. And, what we would ask for -- what staff would ask to do is review our product or have the ACMUI to review our product before it goes to the Commission.

MEMBER PALESTRO: Okay, so then the staff is going to put together, if you describe it, a product, and it'll come back to the Subcommittee to review and to make comments on?

MR. BOLLOCK: Correct.

CHAIRMAN ALDERSON: Well, I think we're going to have several comments now.

All right, Dr. Dilsizian's hand I saw next.

MEMBER DILSIZIAN: I guess the simple

question that comes up is, would you have information that the Subcommittee does not have?

What, you know, for example, whatever the research that you're doing besides teaching and training with the issues is where did 700 hours come from?

I guess the question is, would you have additional data that they may not have that you may share with them as you're doing your work?

MR. BOLLOCK: Right now, I don't believe we have anything -- any information that you don't have or haven't had access to over the past couple years of working this.

But, if we do find -- if we think we've come upon some other background information, we can share that through -- we have a staff resource for your Subcommittee. I believe Maryann's the staff resource. If we come across that, we'll -- Maryann can share that with the Subcommittee, absolutely.

Yes, we don't intend to -- yes, this is -- we don't have -- right now, we don't have any really different information or new information that the ACMUI doesn't have.

But, staff has to come up with our

recommendations to the Commission.

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

MEMBER ENNIS: So, I guess what -- I don't know the words other people must, but I think we're used to a little process where we've had kind of had sort of given you advice and then you've kind of digested that and come up with a position paper.

And, I think the tension here is like it seems to not be following in that kind of a sequence now. And, I don't want to put words in Chris's mouth, but maybe Chris wants to know how his Subcommittee can still impact your paper if you're working in parallel instead of in sequence?

MR. BOLLOCK: It's a good question. We have, I mean, we essentially have our time line, it's coming up shortly. We've had a lot of other projects that have taken precedence the whole way so this is one we really have to focus to get this out.

And, we have heard and, you know, we do from the interim report that we just heard last week and the previous reports, the May or the March 2016 report and all the work on that. I mean, that'll help -- that helps inform staff on our position.

But, and we understand there's, you know, things take time, but we are on a time -- we are on a kind of a strict time line.

And, that's why we're, in this case, we're driving -- it's our evaluation. It's staff's evaluation. So, we're driving this a little bit more so than things in the past that the Committee has seen where you bring an issue to us and recommend change and then we might take action with that.

This is something that we've been directed, staff's evaluation. So, we have, you know, this is something we have to do.

Yes, I don't like to be duplicative in the work. And, the Subcommittee, you know, like I said, for anything to make any actual change that the Commission decides to have us do, say, hypothetically, they have us go the path of rulemaking and we'll have to develop a regulatory basis for that.

We'll have our part of it and there's other parts that tie into it. And so, the Subcommittee's work will tie into that and other public comments will all tie into that process.

So, it is duplicative, but it's -- we will be seeking all that duplicative input or, you know, opinions. We will be seeking all that for anything going forward.

Yes, so, I mean, I understand. This is a little bit different from what the Committee is used to with projects we have. I guess something -- it is probably closest to what we did with the patient release paper.

We had the patient release draft SECY paper. We were driving that. I know the ACMUI had years prior given presentation and that was part of our staff's paper.

And then, we provided the Subcommittee and the full Committee the draft paper. You provided us your recommendations. That's closest to what we're doing right now with this.

CHAIRMAN ALDERSON: Okay, Dr. Ennis, again?

MEMBER ENNIS: So, just to close the loop, so, it seems like the issue is that you have a deadline from the Commission.

So, is it possible to share with the Commission that this is a big deal and it needs more

time to kind of get things aligned rather than --

MR. BOLLOCK: They're aware. And, they're aware that this is -- and this has evolved even with the ACMUI and the discussions from March 2016 to now, right? There's new things happened, you know, you hear new input, you get the new information comes along. Right?

This is -- we have to be able to be flexible with that. The Commission is aware and they have been aware. I mean, I think, I believe, Dr. Palestro, you've briefed them in March of 2016 on this topic.

MEMBER PALESTRO: And 2017.

MR. BOLLOCK: And 2017. And again tomorrow.

MEMBER PALESTRO: And 2018.

MR. BOLLOCK: So, they have been aware. It is just, you know, we owe the Commission. We work for the -- we're staff, we work for the Commission and we owe them this evaluation.

MR. OUHIB: I guess just along that same line, are there, for better coordination and to really resolve these issues, are there any target dates for each one of these at this point?

MR. BOLLOCK: So, the Part 35 rule change implementation, that -- once the rule is -- there's not, again, this is -- right now, it's out of our hands. When it comes back and it's actually published, we'll have six months before it's applicable.

And, in that time frame, we will have -- that's when we'll have to have the NUREG-1556 updates. But, I think we're very close on that right now.

1556 updates that apply to the rule change, I should be specific with that. The general NUREG-1556 updates, that may take a little bit longer. There's -- that may lag a couple months.

The -- so that'll all be done within the six months before it's applicable.

We have to update our internal procedures, our inspection manual chapters and inspection procedures that may have to be changed. I don't believe there's any major changes to those, but Donna-Beth and Maryann are reviewing all of those.

We have some other internal NRC procedures, processes, some of the reporting

requirements change in the rule which means our headquarters operations officer who received the emergency notifications, they have to change their processes. They have to understand what they are receiving.

We also plan on providing training to NRC license reviewers on the spectrums on the changes to the Agreement States as well. And then, to the licensees. So, we'll be developing and providing webinar training on the changes to the rule. And, that'll all happen in the six months.

Essentially, we plan on having that. Once the training's developed, start giving it probably April, May, June and throughout the summer through multiple times.

The Germanium/Gallium generators, that update, I believe we have a draft update already. We're just -- staff will do a peer review before it'll come to me and then we'll send it to the Agreement States for their review and our Office of General Counsel review. So, that's kind of in process now. And then, we'll share it with the ACMUI when we share it with the Agreement States, I believe. So, that may be coming out shortly.

There's actually not a lot of changes to that from what the guidance that was already developed two years ago.

Sometimes when we have -- we'll have to take a look at it. Sometimes we do request -- in the past we have requested with 35.1000 guidance where there's very, very small changes with -- after speaking to a couple -- just a few of the ACMUI members, if the changes are not significant and we've checked with a couple of the ACMUI staff. They said this isn't worth your time to do a full review, full Committee comment.

This is actually maybe the case with the Germanium Gallium generators. There's not a lot of changes to make it generic, which is a good thing. I mean, it makes it -- this makes it easier for future generators and other companies that want to develop future generators.

So, we do -- those are a couple things that we know we'll see in the next couple months and this year that may be coming to the Committee.

Our hard line dates, the only one -- the only two that we really have hard line dates for is the -- to have the rule change implementation in

place and that's just once the SRM goes out before it becomes -- before it's applicable then we'll have to have those in.

And, you know, we feel we can -- we should be able to easily do that.

The patient release, the Reg. Guide 8.39 update, we have a date for that. There is some time frame with Reg. Guide updates, it has to go out for public comment. So, that does delay it. But, it'll be about two years from now when that's fully completed.

And then, the training and experience paper, that's -- that we know we owe at the end of August.

CHAIRMAN ALDERSON: Yes? Dr. Zanzonico?

VICE CHAIRMAN ZANZONICO: So, Pat Zanzonico.

So, regarding the Reg. Guide which you just alluded to, so, I'm glad to see you probably follow the ACMUI recommendations to maintain Reg. Guide 8.39.

I think one advantage of Appendix U over the Reg. Guide is that the Reg. Guide, at least the original version, was largely I-131 focused.

Whereas, the Appendix U was more general.

Are the anticipated revisions of Reg. Guide 839 including generalizing it somewhat to other isotopes, radiopharmaceuticals and so forth?

MR. BOLLOCK: Right now, I believe the tables in there include other isotopes.

VICE CHAIRMAN ZANZONICO: I'm trying to recollect that.

MR. BOLLOCK: Yes, in Reg. Guide 8.39.

And, originally, the Reg. Guide and the NUREG-1556, Volume 9, Appendix U were identical at one point. They did start out identical. We're just hoping to get back to that.

It will be -- it will cover -- it is intended to cover all isotopes or all uses and what tool to be used.

VICE CHAIRMAN ZANZONICO: I guess what I was thinking of was the kinetic models specifically for I-131.

MR. BOLLOCK: Right. So, the modeling that we use in our paper were specifically for I-131. That still is kind of the bounding isotope for patient release, is still I-131. So, the -- I mean, there is more information on that. So, the focus

can seem to be like that, it's not intended. The guidance itself is for all patients.

VICE CHAIRMAN ZANZONICO: Okay. I was just mis-remembering.

MR. BOLLOCK: Yes, no, it's --

VICE CHAIRMAN ZANZONICO: It's one of those -- essentially one of those tables or the four tables in Appendix U or essentially reproduced in the Reg. Guide?

MR. BOLLOCK: They are, yes, they are the same. In fact, I think they came from the Reg. Guide originally in Appendix U.

The one thing of note, so the Reg. Guide, we do understand that the calculations in the tables are out of date. To do those updates, we actually have to split the Reg. Guide updates into two.

It will be one that's including -- one will include the information that was the best practices and all the information that we gathered, staff gathered, ACMUI helped us with in reviewing that.

A lot of that was the information notice that we put out last year. That update, we're going

to do immediately in the next two years.

To do -- to update all those -- the calculations in the tables, that's a lot of number crunching that, frankly, the NRC doesn't do a lot of frequently. So, we contract that out. We need money to contract that out. So, that goes to our budget.

We're planning on asking for the money and that budget will be approved later this year.

So, I just can't tell for sure.

VICE CHAIRMAN ZANZONICO: Just a follow up question on the updating the data. You mentioned contracting that out, that generally is something like Oak Ridge does it?

CHAIRMAN ALDERSON: Dr. Palestro?

MEMBER PALESTRO: Yes, I'd like to bring the discussion back to training and experience again. Because, I really want to try to get this clarified for the Subcommittee.

And, again, I just want to go over the concept that you have in mind. I don't know how far along you are in the project, how much of a draft you have, nor am I asking to discuss that with us at the moment.

But, it seems to me that this Subcommittee can be most useful and most efficient in two ways. One is when you put either the entire draft or sections of it together, that would be distributed among the members of the Subcommittee to review and comment on.

And the second is, and you alluded to it before, that if there is information that you may not have ready access to or not know where to go look that we could potentially have a better sense of where to go look, then we could also be contacted for that.

We're looking at -- we want information on, for example, a number of authorized users graduating nuclear medicine programs. We know how to get that and get it quickly.

MR. BOLLOCK: Right.

MEMBER PALESTRO: So, that sort of thing.

But, that's different than having the Subcommittee work in parallel with you.

MR. BOLLOCK: Right. And, we understand that and I think we have, and staff in the past has reached out to either individual members or a

Subcommittee when we're working out things. And, we have found that work relationship very beneficial to us in helping us in the development.

And, yes, we are not --

MEMBER PALESTRO: No, I just think that's fine. And, I think, you know, I'm speaking on behalf of the Subcommittee that we agree that we're more than happy if that's the set up that we're going to be reactive rather than, quote, unquote, proactive in this endeavor, that's fine as long as we all are on the same page and clear about it up front.

MR. BOLLOCK: Absolutely. And, we appreciate that. And, we will -- you will be hearing from us and the Subcommittee will be hearing from us.

MEMBER PALESTRO: Sure.

MR. BOLLOCK: Yes, because we understand it. You know, we're -- this is a -- the training and experience, as we heard last week in the public meeting, there are multiple people with multiple opinions and they're all -- they all have valid, scientific, logical basis for everything they say.

All right? We heard it from across the

board all the different sides and ends of the spectrum. And, they're all from professionals, other physicians like yourselves, you know, medical professionals that have a lot of experience in this field.

So, we understand, there is a lot there. We staff just have to come up with our -- what we best can do with what we know and what we're, you know, with our understanding of radiation protection, radiation safety that we understand and our experiences and experiences of regulators to answer the questions and to the Commission what the Commission's asked us to do.

So, we get -- this would -- to make any real change would take -- we need to engage and continue to engage our external stakeholders, the ACMUI to make any final change. Like I said, you know, hypothetically, just to same changes, we would -- we understand, we would have to reach out and there is a lot more information needed.

And, we're going to continue to hear those different perspectives before we land on whatever we're going to land on. And, this is just one part of that is what the staff believes right

now.

CHAIRMAN ALDERSON: So, this is Dr. Alderson.

I would like to make a comment and, at the risk of oversimplification, it seems like the two primary issues here, the one that should be primary to all of us is we work within the NRC is the safe and effective handling of these radioactive sources. That's the number one thing that we have to be worried about.

The thing that we have to balance off against is that problem of patient access.

Those are the two sides of the equations -- of the equation.

The pressures, and there are pressures coming on both the medical side and the regulatory side. But, could be extremely different, different pressures for different reasons.

Accordingly, I would suggest that the Committee not be reactive, that the Committee be proactive, really get to work looking at those issues, come up with what you think the medical, you know, best solutions are.

And then, when you get access to the

draft from the NRC, you are already -- you've already got a medical opinion ready.

I think what'll happen is that things will often get rushed toward the end. And then, suddenly, there will be not enough time or it won't be easy to think it through and you shouldn't, I think, just react to what comes out, but actually be ready with a position of our own that we think is both safe and effective and provides as much access as possible, as possible, not universal access, as much as possible within the context of safety.

And, I think it will take some work to do that, but I would go ahead and do that proactively, that would just be my suggestion.

Yes, yes?

MR. GREEN: I understand what you're saying, Phil. And, I think it makes sense provided that there is frequent interaction between staff and the Subcommittee.

Rather than the Subcommittee preparing a document in isolation and the two groups meeting, say, three to four months down the road then they could diametrically opposed.

CHAIRMAN ALDERSON: Yes.

MR. GREEN: Better that there be frequent communication either between, you know, several members of the staff or the liaison on a periodic basis to say, look, this is what we're thinking, what are you thinking and vice versa.

CHAIRMAN ALDERSON: Good. I think that would be served mutually proactive. I think that'd be ideal. Yes.

Yes, Dr. Dilsizian?

MEMBER DILSIZIAN: I guess the time line of August, end of August is interesting because we're not going to meet as a group until September. Which means that a lot of the dialogues happen between the Subcommittee and the staff, but we who are not in the Committee are going to be out of this discussion.

I guess is, the question is, can we have any conference calls in between so that we all are informed?

MR. BOLLOCK: Yes, so, typically, we would, you know, as we did with the patient release paper earlier this year. The Subcommittee was provided the paper, the Subcommittee reviewed, shared -- and then, the entire Committee reviewed it

and discussed it in a public setting on a teleconference. I believe it was a teleconference earlier this year.

We would do the -- we would have to do the same thing, you know, late spring or early summer after you've had a chance to review it and provide -- the Subcommittee provide the input and then the rest of the Committee see it and discuss it.

So, there would be another public teleconference. And, we do recognize that that we need to do that.

CHAIRMAN ALDERSON: Yes? Ms. Weil?

MEMBER WEIL: I think it would be a good idea for this Committee to review the charge to the Subcommittee and make sure that the role of the Subcommittee is clear.

Because, I think this is quite different from what we envisioned our charge to be.

And, you know, going forward, again, there's this question of educational memory which is, since it's an ongoing Subcommittee, it should just be clarified.

CHAIRMAN ALDERSON: I think that's fine.

MR. BOLLOCK: Yes, and we recognize the -- right, and the original charge of the Subcommittee was to look at all modalities and go through a systematic approach going through every one of the -- each section of Part 35.

And, this is a more specific task that we would be asking the Subcommittee to review is our -- and so we -- yes.

(Off-microphone comment.)

CHAIRMAN ALDERSON: Was that comment --

MR. BOLLOCK: At the time --

CHAIRMAN ALDERSON: I don't think the transcriptionist heard that comment, Laura.

MEMBER WEIL: That's probably fine.

(Laughter.)

MR. BOLLOCK: Hindsight's 20/20, at the time, I believe that the Subcommittee was formed with all the best intentions and we're doing all the right things.

CHAIRMAN ALDERSON: Yes, clearly the current charge, whatever it is, I don't remember exactly the charge, but right now, it's focused on one particular set of radionuclide therapies, not the broad concept. That's still there and should

ultimately be addressed.

But, this is aimed at a much more specific target in part because it's come down that way from the Commission. So, we can only -- we have to respond.

And, we have a comment from the audience.

MS. KUBLER: Hi, Caitlin Kubler with the Society of Nuclear Medicine and Molecular Imaging again.

I would ask that, if the ACMUI Subcommittee is to have another conference call, if the public would have a little more advanced notice than a week or a few days to review the Subcommittee's report.

Last time, we kind of scrambled to put together some comments and it would be helpful if we had a little bit more time to thoroughly review that before the teleconference occurs.

Thank you.

MS. HOLIDAY: Hi, Caitlin, this is Sophie.

If I could follow up with your comment, per the ACMUI bylaws, meeting materials have to be

distributed to the Committee no later than two weeks in advance of the meeting.

Of course, that also means that, if I was to receive it, you know, on that two week deadline, I would have to send it out. But, I also have to enter it into ADAMS and then it has to be processed by the staff here in order to make it publically available.

Then, once it's publically available, I have to pass it on to the web contractors for them to post on the website.

So, there is a little bit of lag time, but I recognize that. So, how I take it, as lessons learned from the February and the March teleconference is that I will be proactive and I will send out the report as soon as it's declared as publically available in ADAMS.

Because, recognizing that there is a lag time between the time it's declared in ADAMS to be publically available and posted on the website, I will distribute that at least to our typical professional societal organizations that know will be submitting comments.

And, quite possibly sending it out on

the medical listserv announcement in time for the meeting. But, generally, by the time it gets on the medical listserv announcement, it's also concurrently the time it's posted on the website as well.

MS. KUBLER: Thank you, I appreciate that.

MS. HOLIDAY: Thank you.

MR. BOLLOCK: Yes, we, unfortunately, just we, you know, work the paper, we give it to you for review. You provide us comments. And, it does take time and we have to set up the meeting.

You know, we do our best, we recognize that and we do try to get the information and share it and be as transparent and as early in that transparency as we can. We do our best, but, you know, we do strive for that.

I know the staff strives for that. You know, we do it all the time and sometimes we -- unfortunately, it doesn't get out until, you know, right before the meeting or two weeks before the meeting.

But, we do work to get it out as early as possible.

CHAIRMAN ALDERSON: Mr. Ouhib has another comment.

MR. OUHIB: Yes, on the proactive proposition, I would say perhaps, if you were to identify certain items, let's say training and experience papers, certain items that will probably need to be looked at or reevaluated or whatever, I think it would be probably valuable if the Subcommittee were to know that ahead of time prior to having a conference call and whatnot.

And, say, here are the things that you might want to think about. This is what we're looking at or whatever. So, that way, the Subcommittee would prepare themselves or get something to sort of propose or counter or whatnot.

CHAIRMAN ALDERSON: Do we have any other comments on this subject at this particular time?

Seeing none, I think that we are at a point where we will be adjourning for a break of --

Yes, Dr. Palestro would like to --

MEMBER PALESTRO: Yes, separate topic, I'd just like to inform the Committee that I did hear from the Society of Nuclear Medicine and Molecular Imaging the ACMUI CE session was, in fact,

approved and it'll be held on Monday, June 25th from 3:00 to 4:30 p.m.

CHAIRMAN ALDERSON: Good, well, that's excellent news. Thank you very much. Are there any other items that will need to be brought before us before we take will amount about a half hour break. Then, we're supposed to reconvene at 3:00 and it's now, you know, 2:27 according to that clock. So, we'll take a 33 minute break and that'll be a closed session. This terminates the open session for today. Is that not correct?

MR. BOLLOCK: That's correct.

CHAIRMAN ALDERSON: That is correct.

So, seeing no other comments in the room, are there any comments from outside? I guess there are not any at this particular point. So, we will adjourn and we'll be back for the next closed session starting at 3:00 p.m. Thank you.

(Whereupon, the above-entitled matter went off the record at 2:25 p.m.)