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NUCLEAR REGULATORY COMMISSION

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ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

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TELECONFERENCE

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TUESDAY, SEPTEMBER 22, 2020

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The meeting was convened via Teleconference, at 12:15 p.m. EDT, Darlene F. Metter, ACMUI Chairman, presiding.

MEMBERS PRESENT:

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RONALD D. ENNIS, M.D., Member

RICHARD L. GREEN, Member

HOSSEIN JADVAR, Member

MELISSA C. MARTIN, Member

MICHAEL D. O'HARA, Ph.D., Member

ZOUBIR OUHIB, Member

MICHAEL SHEETZ, Member

MEGAN L. SHOBER, Member

HARVEY B. WOLKOV, M.D., Member

NRC STAFF PRESENT:

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12:21 p.m.

OPERATOR: Welcome and thank you for standing by. All participants are in listen-only mode until the question/answer session of today's conference. At that time, you may press *1 on your phone to ask a question.

I would now like to turn the conference over to Darlene Metter. You may begin.

CHAIRMAN METTER: Thank you very much and good afternoon and welcome to Day 2 of the 2020 Fall ACMUI Meeting.

Our first speaker for this afternoon session is Ms. Lisa Dimmick of the NRC who will provide an update on Medical Radiation Safety Team activities.

Ms. Dimmick.

MS. DIMMICK: Thank you, Dr. Metter and good afternoon, everyone. So, as Dr. Metter mentioned, I'm going to provide an update from the Medical Radiation Safety Team on a number of initiatives that have been ongoing and some updates on some post items.

Next slide, please.

First, I wanted to talk about the Medical Team's activities as they relate to COVID. So obviously, in late March, the reality of COVID-19

pandemic was apparent. The NRC quickly became aware that medical licensees and other facilities were going to need to implement policies to minimize the spread of COVID-19 to their staff, patients, and the public. And in doing so, it may impact medical licensees' ability to perform some of their NRC regulatory requirements.

So with that, the Medical Team developed a template and guidelines to allow the NRC's regional license reviewers a way to quickly process requests that the NRC could expect to receive for specific temporary exemptions. Temporary exemptions that the staff anticipated early on were additional time that would be needed to complete certain tasks like dose calibrated calibrations, annual retraining requirements, and leak test requirements.

Staff also recognized that licensees were probably going to need additional exemptions beyond what staff had initially anticipated. And for that reason, the staff held a public meeting on April 22nd to provide preliminary information about how to request regulatory relief and the regulatory relief pathways available for medical licensees, but also to gather feedback from medical licensees on the types of exemptions they may need.

So the meeting summary for that April 22nd is available in ADAMS using accession number ML20122A253.

Additionally, the ACMUI formed a subcommittee, the COVID-19 Subcommittee, and then held a public meeting on April 30th on its draft report "Proposed NRC Regulatory Relief Options During COVID-19." The subcommittee report is available in ADAMS using accession number ML20125A148.

It was the input from the medical community and the ACMUI, this really did help the NRC to update the list of regulations for which the NRC is and was prepared to expedite a request for temporary exemption.

On May 5th, the NRC issued a letter specifically to all NRC medical licensees providing information regarding licensees' requests for temporary exemptions from certain Code of Federal Regulations and Parts 19, 20, 30, and 35 requirements during COVID-19. That May 5th letter explained that the NRC is prepared to expeditiously review temporary exemption requests submitted by individual licensees and that the objective of this expedited review process is to facilitate the processing of licensee requests for temporary exemptions from certain regulatory

requirements to ensure that the requirements do not unduly limit licensee flexibility using personnel resources in a manner that most effectively manages the impacts of COVID to maintain the safe and secure operations of licensed activities.

Additionally, these temporary exemptions would, if granted, facilitate the licensees' implementation of its radiation safety program in a manner that does not conflict with practices recommended by the Centers for Disease Control to limit the spread of COVID-19.

The May 5th letter also included a table that lists Parts 19, 20, and 35 requirements for which the NRC may consider for expedited temporary exemptions. The May 5th letter can be found in ADAMS via the accession number ML20126G385.

All of our COVID documentation, letters, and tables are also posted on the NRC's Medical Use Licensee Tool Kit.

Next slide, please.

So our efforts didn't stop in May. We have updated the Tables of Regulations for which we could expedite an exemption review, a few times, and most recently, the very end of August. And that table can be found using accession number ML20233B145.

So the Medical Team has continued to review information received from medical professional societies and licensees, regarding the impact of COVID on their facilities.

The other area where we've done some work with regard to exemptions were virtual training requests or modifications to training. The four professional societies penned a letter, the letter was from the American Society of Nuclear Cardiology, the Society of Nuclear Medicine and Molecular Imaging, American College of Radiology, and the American Society for Radiation Oncology. These four societies requested that the NRC consider generator eluting system training as a potential area for regulatory relief during COVID-19.

The letter states that most of the commercial radio pharmacies that supply portions of this training are closed to visiting trainees because of COVID and may not open for the foreseeable future. So obviously, this presents challenge to residents trying to obtain their work experience in that regard. And the professional societies believe that this experience requirement could be satisfied virtually by demonstrated and interactive educational webinars.

So on September 18th, staff replied to the

professional societies and stated or indicated that the staff is prepared to consider, on an expedited basis, requests for an exemption to the generator eluting system work experience described in 35.29(c)(1)ii)(g). However, as such, the training requests for this exemption from this training needs to be submitted by the licensee or by recognized medical specialty boards.

So the Certification Board for Nuclear Cardiology, or CBNC, has requested relief from the regulatory requirement for the training -- or the supervised work experience training requirement involving generator -- involving eluting generator systems. So the NRC did process CBNC's relief request for the exemption and did grant that request in a letter dated September 17, 2020. That accession number is ML20252A174. And the exemption language provided in that letter states that CBNC is temporarily exempt from the NRC recognized Medical Specialty Board work experience requirement in 10 CFR 35.290(c)(1)(ii)(g). Individuals seeking board certification may fulfill this work experience requirement virtually rather than hands on from January 31, 2020 through December 31, 2020. Notwithstanding the regulatory relief provided in that exemption, a licensee that uses generator

systems should, as soon as safely possible, provide hands-on work experience involving the tasks described in that regulation to its authorized users that have obtained the work experience virtually.

The other area where we've processed a training modification is with NorthStar. Staff is finalizing the addendum to the NorthStar radioisotopes RadioGenix Moly/Tech generator system licensing guidance for medical use licensees, medical use committees, and commercial nuclear pharmacies, revision 1, that issued in January 2020. The addendum describes a two-step training program that has been proposed by the vendor due to travel challenges to the vendor's facility due to COVID. So again, this is just an addendum to the licensing guidance. It's providing provisions for a two-step training process for authorized individuals obtaining authorized user status for this particular generator system. We do expect that addendum to be issued very soon and this will be the method that NorthStar will be using to deliver the training for the foreseeable future.

We also are reviewing a proposal submitted by Elekta for its vendor training and how it will deliver the hands-on training portion of its vendor training. The NRC staff finds its proposal acceptable and will

finalize a response for the Elekta request as well.

Next slide, please.

Okay, so the update on authorized user training and experience, in SECY-20-0005, we're making plans for training and experience requirements for unsealed byproduct material, dated January 13, 2020, ML19217A318.

And in this SECY paper, the staff recommends initiating a rulemaking to provide the training and experience requirements for authorized users of unsealed byproduct materials in that to require the physicians be certified by an NRC recognized or Agreement State recognized medical specialty board to become an authorized user.

The recommended rulemaking would continue to assure radiation safety for workers. The Agreement States and the NRC would retain oversight of training and experience through implementation of revised medical specialty board recognition criteria and periodic auditing of recognized specialty boards.

The staff's evaluation and recommendations to the Commission for training and experience carefully considered a wide variety of viewpoints on training and experience including professional societies, the Agreement States, and the ACMUI. The staff's

recommended option shifts more responsibility for credentialing of authorized users to the medical community, while the NRC and Agreement States maintain oversight of training and experience through the recognition of medical specialty boards that demonstrate their training programs meet certain high level, performance based radiation safety competency requirements.

The staff does recommend that their option is it can change the current training and experience paradigm in that the authorized users are credentialed by the specialty boards and the NRC and the Agreement States would no longer review and approve training and experience for authorized users and that authorized users may no longer be listed on medical use licenses.

However, this transformative approach to T&E could better prepare the national materials program for the expected growth of nuclear medicine and the potential for increased radiopharmaceutical use in different fields of medicine.

So the SECY paper is still being reviewed by the Commission, so we're awaiting Commission direction on the Commission paper. I did want to note that the Commission continues to receive letters from the public concerning training and experience and the

interest of other groups, other physician groups, urologists, for example, recommending a change to training and experience or supporting a change to training and experience.

Next slide.

Okay, patient release. Just to recap, in January of 2018, staff submitted or provided the Commission with an information SECY paper, SECY-18-0015, Staff Evaluation of the U.S. Nuclear Regulatory Commission's Program Regulating Patient Release After Radioisotope Therapy. That document can be found using accession number ML17279B139.

Again, that was information to the Commission paper, not a vote paper on the part of the Commission. That's the paper that staff identified that the Regulatory Guide 8.39 could be improved with better instructions provided in that document and we also described the phased approach in that SECY paper for updating Regulatory Guide 8.39.

Anyway, last spring, May of 2019, NRC staff did develop a brochure that we have in our medical toolkit, specifically in our patient release portal. A brochure entitled, "What You Should Know About Treatment for Radioactive Drugs." That accession number is ML19121A242.

And the committee is aware that we did update the Phase 1 or we did the Phase 1 update to Reg. Guide 8.39 in April 2020 and that document can be found using ADAMS accession number ML19232A081.

Next slide.

So we also in the spring received a request for a rule change from Peter Crane and that petition was docketed on April 13th of 2020. However, that petition has subsequently been withdrawn by the petitioner on July 10th of 2020. So currently, there's not an active petition in-house for concerning patient release.

So what's next for patient release? You may recall in our spring meeting or in a prior meeting, we discussed possibly developing a patient release video. We are moving forward with that at some point soon. The ACMUI will get a chance to take a peek at that video, but our target release for the video is in November. It's a very short video about 30 seconds just trying to emphasize good practices using time and distance and good hygiene with regard to petition construction.

The other last item with regard to patient release is regarding the Phase 2 update to Reg. Guide 8.39. The target release, meaning final document,

we're looking at spring of 2022 when that document would be finalized. So there will be an opportunity probably next spring to begin reviewing this document in a public fashion for comment on the updates to Reg. Guide 8.39 that includes the dosimetry model methods and calculations.

Next slide.

Okay, moving on the emerging technologies. So staff has been evaluating how we evaluate emerging medical technologies and develop licensing guidance for those technologies. So we've identified that our process had room for improvement so it could be streamlined. So we have been working on a new process to streamline how we review and issue licensing guidance for emerging medical technologies.

You see our new process will provide a cost savings in both time and staff resources. The process still remains inclusive of NRC regional, Agreement State, and ACMUI contribution to the license guidance development. And we also see that the new process does ensure consistency and a more uniform approach to developing the licensing guidance.

Next slide.

We anticipate we have maybe a six-month savings in the time it takes to draft and issue licensing

guidance for a new emerging medical technology. And in this process we'll have a Medical Team individual with support to draft the licensing guidance.

What's new to the process is use of a standing committee on emerging medical technologies and this standing committee is made up of an Agreement State's co-chair, NRC co-chair, NRC's regional general counsel, a regional staff member, another Agreement State member. And the role of this committee is to simply provide the checks and balances in determining whether or not a new technology should be developed as a new emerging medical technology for licensing guidance or if the new technology does, in fact, meet the criteria for a 35.1000 technology and that to continue the licensing guidance development.

The Agreement States and regions as I mentioned must still review the document. There's really no change in that process or how these reviews were done. That really stays the same. Once all of the comments are received from the standing committee, the ACMUI Agreement States and regions, the comments are resolved and then move forward for signature and issuance of the licensing guidance.

So then we anticipate, we're able to call off about six months of time, start to finish of this

license guidance development for new emerging technologies. We do anticipate we will be rolling this out a little bit later this fall. There are a couple of technologies that we're interested to put into this process. So more to come to the ACMUI on our emerging technologies here in the very near future.

Next slide.

So another area concerning emerging medical technologies is the emerging medical technologies rulemaking plan. So NRC staff has been working on a rulemaking plan to codify licensing requirements for emerging medical technologies and also to address calibration and dose measurement issues for the strontium-rubidium generators. So currently strontium-rubidium generators don't fully meet the calibration and dose measurement requirements in Part 35, so NRC has used enforcement discretion in review situations.

So in this emerging medical technologies rulemaking plan, we are taking this as an opportunity to address the strontium-rubidium generator issues with regard to calibration and dose measurement. But in addition to that, the options that we're looking at would be just codifying certain requirements for certain emerging medical technologies like

Microspheres and Gamma knife and also -- or another option might be to codify a more performance-based requirement that would allow all of the emerging medical technologies that we have evaluated under Part 35 and then some to maybe more broadly fit into Part 35.

So this rulemaking plan will be going to the Commission the end of December or some time in December. It is expected that the ACMUI will receive a courtesy copy of the draft rulemaking plan in October. So next month, just a few weeks away, the ACMUI should get a copy of this rulemaking plan for your awareness and review.

There won't be any action for the ACMUI with regards to the rulemaking plan until the rulemaking plan has been deliberated by the Commission and then we receive Commission direction on the options that are proposed in the rulemaking plan. So if the rulemaking plan should go to rulemaking at that point in the future, there would be more work on the part of the ACMUI. But at this point, this is just a courtesy to review the rulemaking plan going to the Commission.

Next slide.

Okay, extravasation. I have a couple of slides here. So on March 17, 2020, the NRC provided a report for the U.S. Senate Committee on Appropriations

and U.S. House of Representatives Committee on Appropriations. That accession number in ADAMS in ML20050W302.

The NRC developed this report in response to requests in the House of Representatives Report No. 116-83 entitled "Energy and Water Development and Related Agency Appropriations Bill 2020" and Senate Report No. 116-102 entitled "Energy and Water Development Appropriations Bill 2020."

Specifically, these reports called on the NRC to provide updates to injection quality monitoring, classification, and reporting requirements with regard to extravasation and the report was due no later than 90 days after enactment of Public Law 116-94 entitled "Further Consolidated Appropriations Act 2020."

So in that report, this identifies that currently the NRC does not classify radiopharmaceutical extravasation as medical events and thus does not require them to report it to the Agency. However, considering recent advancements, and anticipated advancements in nuclear medicine therapy, the NRC staff is reevaluating this position.

The congressional report provides a brief summary of the NRC's activities related to extravasation, the considerations informing the NRC

staff, ongoing evaluation, and planned next steps. So currently the Medical Team is determining whether there is a need to revise the NRC's current policy of excluding radiopharmaceutical extravasation from medical event reporting.

The NRC staff is considering whether extravasation should be reported, but it has not -- staff has not yet made any conclusions. If the NRC does determine extravasation should be reported, NRC would establish the reporting criteria such as reporting those extravasations exceeding the current criteria from medical events or if the criteria of those extravasations causing permanent functional damage to an organ or physiological systems or whether a different reporting threshold should be applied and whether distinction should be made between diagnostic and therapeutic extravasations. These are some of the things that were communicated in the congressional report.

Next slide.

So on May 8, 2020 Lucerno Dynamics submitted a petition for rulemaking PRM-35-22, requesting that the NRC revise its regulations to require medical event reporting of extravasation that resulted in a localized dose exceeding 50 rems. The

petition was accepted for docketing and then subsequently on September 15th the Federal Register notice announcing a 75-day public comment period from when the petition was published. The public comment period closes on November 30th of 2020, so November 30, 2020. Please note that in the FRN there are a series of questions regarding detecting and reporting extravasation. I would encourage the public in this meeting, as well as the ACMUI, to familiarize yourself with those questions and consider responding to the Federal Notice solicitation.

Also note that there is a petition working group that is evaluating the petition and it is this petition working group that will determine staff position on whether to accept or deny the petition and that's expected to occur in the June '20-'21 time frame.

Next slide.

Okay, the Medical Team is coordinating the evaluation it's conducting on extravasation of whether extravasation should be reported as medical events as well as the reporting criteria with the petition review working group, so we do need to align our respective efforts because the Medical Team's evaluation will provide input to the petition review working group.

So the staff's technical evaluation, we

are evaluating extravasation, but we keep a few things in mind as we're going through our evaluation. The questions, the questions to answer in our evaluation and then subsequently forming any recommendations or options, but we need to evaluate is extravasation preventable? Is it preventable with current technology or does technology need to be developed to detect extravasation or prevent extravasation? Is extravasation the practice of medicine concern or a regulatory concern? Or is it a combination of both or where is the line in the sand of when it's practice of medicine versus when it becomes maybe a regulatory concern, if that's the case.

Is the dose consequence from extravasation significant enough to merit regulatory reporting, or merit a change to policies? These are the things that we're keeping in sight as we continue our evaluation.

Please be aware, we are planning a public meeting on extravasation. This is separate from the rulemaking initiative. This is a public meeting that NRC staff is hosting -- will be holding as part of the Medical Team's evaluation, but we are planning a public meeting on December 8th.

So next steps with regard to ACMUI on this, we do anticipate we'll have a document for ACMUI to

review in January of 2021, a document of sort summarizing the NRC staff's evaluation and any policy options or recommendations that we may see that should be considered for extravasation. So in providing that type of report to the ACMUI, again, it will be forming a subcommittee or directing the current Extravasation Subcommittee to evaluate this report and then provide your recommendations back to NRC staff and then holding a public teleconference to discuss the report. So we're probably looking at the April, late March-April 2021 time frame for our public teleconference with the ACMUI on extravasation.

And so staff does plan to complete our technical evaluation the end of April, very beginning of May. Again our technical evaluation we're providing input to the petition working group to support the petition working group's final decision on whether or not to accept or deny the petition.

Next slide.

Okay, veterinary release. So while this is veterinary medical release and not medical, the Medical Team is actively involved in reviewing a licensing template application for the release of dogs following treatment for osteoarthritis using a Tin-117m colloid.

The thing that you may not be aware of with regard to veterinary release is that veterinary release or pets are subject to the Part 20 limits for members of the public and not the limits in Part 35 for human release. So the limits in Part 20 for public release are 100 millirems per year and 2 millirem in any one hour. So in order to release pets, they need to meet this criteria for release.

So what's unique with this particular licensing template is that a proposed release procedure contains a pre-screening questionnaire to determine if there's a need to modify any typical interactions that occur between the pet and the pet owner such as co-sleeping, officing, lap sitting, and if these are behaviors that occur, what behaviors need to be modified and how long do they need to be modified in order to meet the limits for members of the general public.

We are wrapping up this evaluation and still reviewing the request, but it's an interesting project for the Medical Team.

Next slide.

Okay, I want to make you aware of some upcoming meetings that the Medical Team is supporting. So on October 14th, we are hosting with the FDA the FDA-NRC Workshop on Enhancing Development of Emerging

Technologies, Radiopharmaceuticals, and Radiological Developments. This is a full-day meeting from 8 a.m. to 5 p.m., again on October 14th. We have sent out listservs about this meeting. It's a long website to read off, but if you are interested to find out more about this meeting and register, it will be conducted by Webex, but the web address for more information is https://www.fda.gov/drugs/news-events-human-drugs/fda-nrc-workshop-enhancing-development-emerging-technologies-radiopharmaceuticals-and-radiological.

So good luck. If there is anyone interested to find out more about this meeting and you're having trouble finding it on any of the posted websites, please feel free to contact me, Lisa Dimmick, lisa.dimmick@nrc.gov, and I'll be more than glad to provide you the information on that meeting.

Okay, then on October 15th, the NRC staff or Medical Team is supporting an AAHP and Medical Health Physics Section Special Session, specifically the topic that day is Therapy Patient Release Issues. So we will be giving a presentation on patient release at that meeting.

And then there is the International Conference on Radiation Safety: Improving Radiation Protection in Practice. This is a meeting being held

by the International Atomic Energy Agency and the meeting is planned -- it's going to be a virtual conference now, but it's November 9th through the 20th. The NRC has several topics for this meeting, but we are giving an in-person presentation -- or presentation on patient release and we also have a poster for the veterinary release on the osteoarthritis using Tin-117m.

And then we have, as I mentioned, we will have the Commission meeting with the -- the Commission meeting with the ACMUI is planned for November 18th from 10 a.m. to 12 p.m.

And then the extravasation public meeting that I mentioned is planned for December 8, 2020 and more meeting details will be provided about that at a later date.

Next slide.

I think that's it other than the acronyms for the presentation going over to another slide. With that, I guess, I can take questions.

CHAIRMAN METTER: Thank you, Ms. Dimmick. Darlene Metter. Thank you for your really very thorough presentation and the Medical Radiation Safety Team's really prompt and diligent work and response to, as you can see, a broad range of medical radiation

safety items and stakeholder concerns.

Now are there any questions from the ACMUI Committee?

OPERATOR: We will now begin our question and answer session. If you'd like to ask a question, please press *1 from your phone, unmute your line, and speak your name clearly when prompted. Your name is required to ask a question.

MEMBER SHEETZ: This is Mike Sheetz. I have a question.

Thank you, Ms. Dimmick for a very interesting and comprehensive presentation.

I have two different questions. One, with respect to the release of in-person training, you had said you are working with Elekta for the vendor training. So will you be granting an exemption to the vendor training from any hands-on aspects to that, specifically the emergency procedures?

MS. DIMMICK: So in Elekta's proposal there again it's kind of similar to what we talked about yesterday with the drills and practice. There's ways that they've found a solution that they can still demonstrate that people will get hands-on training. Part of the training is virtual, but there are still requirements to do hands on. You can't avoid it, but

they're modifying how they're delivering and how they're issuing certificates of completion.

MEMBER SHEETZ: Okay, so there still will be a hands-on portion.

MS. DIMMICK: There still needs to be a hands-on portion, correct.

MEMBER SHEETZ: Okay, that was what I was questioning because that would be inconsistent with what was stated yesterday.

MS. DIMMICK: Yes.

MEMBER SHEETZ: Okay. If you were going to grant it all virtually --

MS. DIMMICK: No.

MEMBER SHEETZ: -- for the initial training and then still require hands on for the annual refresher, I was just kind of pointing out.

MS. DIMMICK: Yes, with the vendor training, there's still things that have to be done hands on and how they achieve it and how they can attest to it or where some maybe differences of what was done before, but it still involves hands-on components.

MEMBER SHEETZ: Okay. Thank you. The other question I had was on the emerging technologies and the new process that you'll be working on. My understanding about this 35.1000 uses about the

compatibility level C of the Agreement States, so they really don't need to come to the NRC with emerging technologies. They can approve them on their own. Is that a correct statement?

MS. DIMMICK: So the regulation at 35.1000 is actually at compatibility D. So some Agreement States don't have that particular regulation. It's the licensing guidance that is developed to support a licensing application. It's actually a compatibility C.

And with compatibility C, it means that the essential objectives of the document need to be met if they're going to use that document or something like that document. But Agreement States wouldn't have to adopt it essentially as written.

So licensing guidance is for Agreement States' compatibility purposes, a program component with a compatibility C. So many states, some states may develop their own type of guidance or use NRC's guidance.

MEMBER SHEETZ: Okay, and then I guess that's my concern which actually goes back to the presentation of 35.1000 uses that Agreement States may choose to license an emerging technology and not even bring it to the attention of the NRC or bring it to

their attention, but there would not be any input and also there would not be any input from ACMUI. So I guess it looks to be sort of inconsistent or some inconsistency.

It would be nice if Agreement States were required to come to the NRC and the report together could come out again with a consistent licensing guidance for emerging technologies rather than having some states doing it on their own and other states working with NRC. But there are certain emerging technologies out there right now that are in Agreement States to which there is no licensing guidance documents in NRC.

MS. DIMMICK: Yes, and emerging technologies are hard. It's a timing -- and with many -- the ones that are truly a novel technology, there's really very little operational experience, so timing is a challenge in trying to provide guidance timely for technologies. And again, sometimes things happen and we may not be fully aware of it or Agreement States can certainly license without the NRC's guidance.

Ideally, we want to be using the same guidance across the country, but for the most part I think that's what happens, but there are some maybe some things that aren't quite in that -- or being done

that way.

And that's another reason why we're very interested in our emerging medical technology rulemaking plan because it will help to get some of these technologies into regulation. And it's not necessarily with the emerging medical technologies rulemaking plan to now in retrospect codify these emerging technologies or technologies we've already licensed under 35.1000, but maybe in the rules moving forward enough that we are aware of how things are evolving so that we can have a rule to maybe include at least the next generation of technologies coming down the pike and it will help in this regard for this reason of developing the licensing guidance for use of emerging medical technologies.

MEMBER SHEETZ: Thank you.

VICE CHAIR SCHLEIPMAN: Hi, this is Robert Schleipman. I just had a question about the extravasation rulemaking recommendations that the medical field is working on. Just thinking logistically, when -- I think the slides mention ACMUI review in early March, but when that might be available for the ACMUI Subcommittee? The ACMUI anticipates that to be in February?

MS. DIMMICK: Yes. We would anticipate

the ACMUI would get it in January because we would provide you at least 60 days to review it.

VICE CHAIR SCHLEIPMAN: Oh, that's great.

MS. DIMMICK: Yes. Our target is we have a specific date on our project plan, but it's January. It's expected that the ACMUI will get it in January of 2021, so in a few months.

VICE CHAIR SCHLEIPMAN: Thank you.

CHAIRMAN METTER: Lisa, this is Darlene. I just wanted to commend the NRC staff for -- I was intrigued by the 30-second patient release video for the public and I just thought that would be very helpful as far as for the public to learn about what we're recommending for them to decrease their doses.

Would it be possible for you all when you publish it to let us know so we can also view it?

MS. DIMMICK: Yes. That's our plan. I just don't have those dates specifically, but it will be soon that you'll have an opportunity to see it before we finalize it.

CHAIRMAN METTER: Thank you. Are there any other questions or comments? Anyone in the public on the bridge line?

OPERATOR: It looks like we currently have a question and just as a reminder for anybody else who

would look to put a question in, *1, unmute your line, say your name, *2 to withdraw.

We do have a question from Carol Marcus. Your line is now open. Carol, your line is open.

(Pause.)

DR. MARCUS: Can you hear me?

CHAIRMAN METTER: Yes.

DR. MARCUS: Okay. Lisa, you talked about NRC auditing training programs for recognized medical specialty boards, if the staff's plan for T&E is accepted by the Commission.

But the NRC has never ever audited any of the programs of the American Board of Radiology in diagnostic radiology or radiation oncology. And I don't think there's a single program in the United States in either of those fields that are compatible with the training and experience requirements for radiopharmaceutical therapy in Part 35.

I wrote a petition a couple of years ago asking the NRC to inspect these programs. They absolutely refused to do anything whatsoever. And so why should we trust that NRC would audit these other specialty boards when it refuses to audit all the radiation oncology and diagnostic radiology programs now?

And nuclear cardiology isn't even a recognized board. The American Board of Medical Specialties turned them down twice. They're an artificial, made up, pseudo board. And the NRC recognizes that even though the American Board of Medical Specialties does not.

So what is this audit promise?

MS. DIMMICK: So just to provide some insights, so if we were to develop a rule on training and experience that language would be developed in the rule in that regard to clarify in some ways that audits are expected with regard to specialty boards.

If you go back to the 2005 Federal Register Notice that published the 2005 updates for specialty boards and training and experience, it discusses in there how NRC would evaluate specialty board performance in looking at medical event reportings and finding relationships between the types of events reported and related facts to training. That's how at that time at least it was intended the NRC would evaluate specialty board performance.

So the previous requirements didn't speak to specifically auditing specialty boards.

DR. MARCUS: It's quite unsatisfactory, Lisa. There are 500 hours of supervised experience

required in radiopharmaceutical therapy and I don't think that the diagnostic radiologists or radiation oncologists get any of it. They get their cases. I don't think very many, if any, get 200 hours of lecture and laboratory in the area of radiopharmaceutical therapy either. Every institution I've ever worked in and these have been broad licensed institutions in California that have residency programs in diagnostic radiology and also in radiation oncology. They never meet them.

When I talked to people in the Office of Enforcement they said oh, well, you know, your request was too vague and when I said well, specifically, UCLA's program is out of compliance. They said oh, that's an Agreement State program.

Then the lawyers in California said that California can't go in and inspect these programs for compliance because the Memo of Understanding is between the NRC and the American Board of Radiology, not between California and the American Board of Radiology.

The bottom line is there are no investigations of training and experience. And in fact, you know, I don't even see why a competent physician needs any of your guidance documents. The physician who is well trained knows darn well what he

should be doing better than the NRC.

I mean yesterday, we saw after 23 years, you still can't get out anything intelligent on patient release. The garbage that's been out for 23 years is garbage.

And you know, California is suggesting people use radar. They've been suggesting that for years. That's what I've been teaching all my residents, use RADAR [RAdiation Dose Assessment Resource]. And don't dare use the made up pharmacokinetic garbage in your regulatory guides.

So I think training and experience is a real problem if you don't inspect the programs. And then you justify all this money and time and people writing regulatory guides for people who don't know what they're doing and shouldn't be licensed in the first place.

MS. DIMMICK: Dr. Marcus, thank you for your comment and we'll keep that in mind as we move forward depending again on how training and experience -- what the Commission decides and directs staff to do in that regard.

DR. MARCUS: Thank you.

MS. DIMMICK: Thank you.

CHAIRMAN METTER: Are there any other

questions?

OPERATOR: Yes. We have a question from Michael Peters. Your line is now open.

MR. PETERS: Thank you, Lisa, for an informative presentation. This is fantastic information.

On the extravasation petition working group making the final determination on the petition, could you expand on the composition of that work group and how it will ensure provider perspectives receive careful consideration?

For example, are work group members reviewing each of the comment submissions on the docket or is the input being summarized for them? Thank you.

MS. DIMMICK: So the petition is in the petition -- it's in the rulemaking process, so there is a group that is evaluating the petition that's made up of Medical Team staff, OGC, I believe. There is an Agreement State. I'll have to confirm the make up of the petition working group and maybe I can get that information while we're on the call. And I'll update exactly who is the make up of that petition.

So they'll receive the comments and evaluate them and draft the decision document. However, it is expected that the Medical Team's

evaluation will provide technical input to the petition group as they're evaluating the petition's merits, the merits of the petition. So there is -- we have -- there are two separate initiatives, the petition initiative and then staff's evaluation, but they will cross paths and the staff's evaluation will provide information to the petition group and we'll probably aid in a petition's decision. So it's not -- so there is a Petition Review Board who will review the documents provided or collected for this petition and then there's a Petition Review Board that will review to determine if the petition has merit and we would proceed with some rulemaking initiative or not.

Then also in the petition process that while a -- if -- this happens with any petition for rulemaking that a petitioner may specify some interest that the rule would be, but in collecting the comments or identifying merits of a petition, what might shape up in a rule plan or the options may not be exactly how a petitioner made the request. Does that help?

So -- but I'll try to get clarification on who is in the rule group. Okay, so we have -- it's NRC staff on the petition working group, rulemaking and Medical Team and Office of the General Counsel on the petition and I think that's probably standard for

all petitions is NRC staff.

MR. PETERS: Did they have -- will the individual work group members have access to each of the submissions on the docket or is that not something they look at. They look more at like a summary of the comments?

MS. DIMMICK: Oh, no. The working group will have access to all of the comments that are submitted and they'll be binning those and evaluating those. I mean that will be part of how they're making the decision.

MR. PETERS: Great. Thank you.

MS. DIMMICK: So the working group will have access to all. If I didn't clarify that -- so the working group has access to all of the comments that are submitted for that petition.

MR. PETERS: Thanks, Lisa.

CHAIRMAN METTER: Are there any other questions on the bridge line or from the committee?

OPERATOR: We have no further questions in the queue.

CHAIRMAN METTER: Thank you. Any questions from the committee itself?

Well, thank you, Lisa. That was an extremely -- very well, put together presentation and

your team has done an immense amount of work and we really appreciate that. Thank you very much.

MS. DIMMICK: Thank you.

CHAIRMAN METTER: Now the next item on the agenda is open forum to discuss topics for the future that may be of interest for future meetings.

Is there anybody on the committee that would like to suggest any specific topics?

Okay, Kellee and Chris, I don't hear anybody from the committee right now. If you do have topics that come up in the interim, you can email them to Kellee, myself, and Chris, and we'll be happy to discuss it and look at that.

Okay, our final is our administrative closing with Ms. Jamerson, to provide the meeting summary and proposed dates for the spring 2021 meeting.

Ms. Jamerson.

MS. JAMERSON: Hi, Dr. Metter. This is Kellee Jamerson and I will go over the summary of the meeting.

So, I did receive some feedback regarding potential dates for the spring meeting. The top three dates were March 22nd -- well, March 15th through the 16th; March 22nd through the 23rd; and April 12th

through the 13th.

Is there any -- or any issues with those top three dates that received the most input, the availability for the ACMUI members?

VICE CHAIR SCHLEIPMAN: Excuse me. What did you say the March dates were?

MS. JAMERSON: March 15th and 16th and March 22nd and the 23rd were the two top dates that received the most input.

VICE CHAIR SCHLEIPMAN: Thank you. And April 12th through the 13th?

MS. JAMERSON: Yes.

VICE CHAIR SCHLEIPMAN: Thank you.

CHAIRMAN METTER: I have no problem with any of those dates.

MEMBER MARTIN: My preference would be either one of the March dates, but I can make either one of them work.

CHAIRMAN METTER: Kellee, do you want just try it with March 15th. That's the first one.

MS. JAMERSON: Yes. March 15th to 16th. Is this the preferred date for the priority dates and then we'll set the alternate dates?

March 15th to 16th is the preferred date?

(Chorus of ayes.)

CHAIRMAN METTER: How about does anybody have a problem with it? Let's look at that.

MEMBER GREEN: APHA is the annual pharmacy convention, but it will be annual and I don't see a problem missing that last day.

CHAIRMAN METTER: Thank you, Richard. That was Mr. Richard Green.

Okay, so it sounds like March 15th and 16th will be our first choice. Is that okay, Kellee?

MS. JAMERSON: Okay. This is Kellee again. Do we have a -- for either March 22nd or 23rd or April 12th through the 13th for the alternate dates.

MEMBER MARTIN: This is Melissa Martin. I'd really prefer the March 22nd, 23rd. I can make the April date work, but it's really tight.

CHAIRMAN METTER: Thank you, Melissa. This is Darlene.

Do I have anybody who would have problem making the 22nd to 23rd of March date?

Okay. I don't hear any, Kellee, so should we vote on making the first option for the spring meeting, March 15 and 16, with the second option being March 22nd and 23rd?

Do I have a motion to make these proposed dates for our spring meeting?

VICE CHAIR SCHLEIPMAN: So moved by Robert.

CHAIRMAN METTER: Dr. Schleipman.

MEMBER WOLKOV: Second, Harvey Wolkov.

CHAIRMAN METTER: And Dr. Wolkov. Great. All in favor, aye.

(Chorus of ayes.)

CHAIRMAN METTER: Anybody abstaining or opposing?

Hearing none, I think these are our dates, Kellee.

MS. JAMERSON: Okay, thank you all.

MEMBER OUHIB: Kellee, this is Zoubir Ouhib. I just have a question. I know Lisa has in her presentation two dates in there. I just want to make sure that these dates do not interfere with some of those dates that she has proposed for things that will be happening.

MS. JAMERSON: Thanks, Zoubir, for that. We will take into consideration the dates that we set for this meeting as well as for the other -- the future public teleconferences that Lisa mentioned.

MEMBER OUHIB: Right.

MS. DIMMICK: Hi, it's Lisa. Yes, so recognizing it may end up winding up that the

Extravasation Subcommittee would actually present at the spring meeting on their report. We will try to keep that in mind, depending on what date gets finalized so that we're able to give the ACMUI the full 60 days. So that we don't have to have a separate meeting, we'll want to try to align it so that we're able to report out on extravasation during the spring meeting. We'll keep that in mind in our schedule.

CHAIRMAN METTER: Kellee and Chris, this is Darlene again. So since we're having our Commission meeting on November 18th, we generally have the Commission meeting in the spring. Will this be then -- we'll be having our 2021 Commission meeting in the fall or should we just wait for the spring with 2022?

MS. JAMERSON: That is something that we would have to coordinate with the Commission whether we'll get back on track and have another meeting in the spring. We're not sure or whether this will be our new pattern to have it in the fall. So we'll have to see. We'll have to work that out with the Commission and their schedule.

CHAIRMAN METTER: Okay. Thank you.

VICE CHAIR SCHLEIPMAN: This is Robert Schleipman. I have a question.

MS. JAMERSON: Go ahead.

VICE CHAIR SCHLEIPMAN: Are we anticipating these will also be virtual meetings or is it just up in the air at this point?

MS. JAMERSON: This is Kellee. Right now it is up in the air. Currently, our Commission meeting in November is scheduled for a virtual meeting or virtual component and in-person as well for those that can be there to present in person, but it is a virtual meeting as well essentially.

And for the spring meeting, we are not sure. It's up in the air at this time.

VICE CHAIR SCHLEIPMAN: Thank you.

MR. EINBERG: Yes, so this is Chris Einberg. Just as an FYI, the Commission has started to hold in-person meetings right now, but they're limiting the audience participation and so they're just limiting to a select group, the speakers, and the support staff, but with the appropriate social distancing and masks. But the Commission has started to have in-person meetings and there is a virtual component for those who choose not to attend or are unable to attend.

CHAIRMAN METTER: Thank you, Chris. Are there any other items that we need address, Kellee, or do you have the summary of the meeting?

MS. JAMERSON: I do. Let me do that next. So this just provides the items in red are what were covered yesterday and today. Yesterday, ACMUI endorsed the Medical Events Subcommittee report as presented.

Also yesterday, following Mike Sheetz's presentation of the Non-Medical Events, the ACMUI recommended to the NRC staff and the Nuclear Medicine, Nuclear Materials Program, I'm sorry, to evaluate the issue of protection of short-lived medical isotopes and municipal waste. This would be waste through nuclear medicine patients that might be triggering the landfill alarms and to provide some regulatory guidance or best practices or additional instruction. This docket takes into consideration and also today, we just scheduled our -- tentatively scheduled our spring 2021 meeting for March 15th to the 16th, 2021 and our alternate date is March 22nd through the 23rd, 2021.

And as of right now, the format of this meeting, whether it be virtual or in-person, is to be determined. This is all that I have for this meeting.

MEMBER MARTIN: Kellee, this is Melissa Martin. I have one question for you or Lisa

Is the meeting that's scheduled for December 8th, the extravasation public meeting, will

that be a virtual meeting?

MS. DIMMICK: Hi, this is Lisa Dimmick. Yes, Melissa, we're planning that to be a virtual meeting.

MEMBER MARTIN: Thank you.

MS. JAMERSON: This is all that I have. I'll turn it back over to you, Dr. Metter.

CHAIRMAN METTER: Thank you, Kellee. Do we need to vote on this on your presentation or we do that at another time?

MS. JAMERSON: We are good. I'm just providing a summary of the action items and recommendations from this meeting.

CHAIRMAN METTER: Okay, well, thank you very much and no other -- Chris, are there any administrative items that we need before closing?

MR. EINBERG: Nothing.

CHAIRMAN METTER: Okay, so everybody, thank you very much for your time and your flexibility and for participating and allowing the ACMUI to continue its work.

Until we meet again, hopefully, sometime in the near future you all have a good rest of the day and thank you again. The meeting is adjourned.

MR. EINBERG: On behalf of the NRC, thank

you also to the ACMUI and to the NRC staff and all the presenters. Thank you.

CHAIRMAN METTER: Thank you.

(Whereupon, the above-entitled matter went off the record at 1:31 p.m.)