Official Transcript of Proceedings

NUCLEAR REGULATORY COMMISSION

Title: Public Comment Meeting on Radiopharmaceutical Extravasations

Docket Number: (n/a)

Location: WebEx meeting

Date: Tuesday, December 8, 2020

Work Order No.: NRC-1269 Pages 1-95

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(202) 234-4433

UNITED STATES OF AMERICA

NUCLEAR REGULATORY COMMISSION

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PUBLIC COMMENT MEETING ON RADIOPHARMACEUTICAL EXTRAVASATIONS

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TUESDAY,

DECEMBER 8, 2020

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The Public Comment Meeting convened via Video Teleconference, at 2:00 p.m. EST, Sarah Lopas, Facilitator, presiding.

PRESENT:

SARAH LOPAS, Facilitator, NMSS/MSST/MSEB

LISA DIMMICK, Team Lead, NMSS/MSST/MSEB

CHRIS EINBERG, Branch Chief, NMSS/MSST/MSEB

KELLEE JAMERSON, Host, NMSS/MSST/MSEB

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

2:01 p.m.

MS. LOPAS: Good afternoon, everybody. Thank you for being here. And welcome to the U.S.

NRCs public comment meeting on radiopharmaceutical extravasations.

In a moment I am going to hand it over to Lisa Dimmick. She is the medical radiation safety team leader in the NRC Office of Nuclear Material Safety and Safeguard. And she is going to give our presentation today. But I'm going to just go over, quickly, some of the logistics for today's meetings.

Next slide, Kellee. Our slides are publicly available right now in our agency-wide documents access and management system. They are in ADAMS. And I did post the link in the chat. If you are able to open up your chat panel.

So, if you haven't already, click on the little chat icon. It's a little bubble and it says chat on the bottom right-hand side of your WebEx. And that will open up the chat panel. And that's where I will be posting some links periodically throughout today's meeting.

The first link that I share up top will take you directly to a PDF of today's slides. So if you're hearing me and seeing the slides, that means your all connected just fine.

A couple of notes about WebEx connectivity. Primarily this has to do with

bandwidth issues, so if you happen to have trouble with you audio, make sure that you shut down all sorts of other applications going on, on your computer.

Sometimes even shutting down, if you have a VPN; that helps. But if you're really having issues and you're connected to your computer audio, go ahead and you can switch your audio to phone.

And you do that by just going up to the menu up at the top on WebEx, to audio and video. And then if you click on audio and video, the first option you should see is switch audio. And that will walk you through how to call in using your cell phone instead.

So, I do want to note that everybody is in listen only mode right now. But feel free to send a chat at any point throughout Lisa's presentation.

And that's what this screen shows. So, there will be two ways to comment when we get to the public comment portion of the meeting, which is going to happen after Lisa's presentation.

So, you can either send a chat or you can raise your hand to be unmuted. And the way you want to do that is just make sure you have the participant panel and the chat panel open.

So if you start at the bottom of this

screen, click on both those icons. If you're going to send us a chat, just type it in that little text message area, the chat message area.

But make sure that you have selected all panelists. I'm not sure what options you all have as participants, but sometimes folks send it to just the host. And that's Kellee.

And Kellee than has to kind of copy and paste it to all the panelists so that we can see it. So make sure you select all panelists when you're sending us your chat comments.

You can also, of course, when we get to Lisa's presentation, feel free to do that at any point during Lisa's presentation if something comes up that you want to kind of quickly get off your mind and send to us. And we'll get to it once we get to the comment portion of the meeting.

But, after the presentation we will be unmuting people's lines individually. And the way that Kellee can know to do that is you have to raise your hand by clicking on that little hand icon.

So, we'll go ahead and call out your name and Kellee will unmute you and let you know that you've been unmuted and you can go ahead and speak. So you don't have to type, you can certainly speak to

us. Let's go to the next slide please, Kellee. Okay.

The purpose of today's meeting is to get feedback from you all. From the medical community and other stakeholders on radiopharmaceutical extravasations and whether they should be reported as medical events. And this input is going to help the NRC Staff with our evaluation of this issue.

Today's meeting is being transcribed. So we have a court reporter on the line with us today. He's joined us as a panelist here.

That meeting transcript is going to be publicly available for you in a couple of weeks. And we really wanted to get this meeting transcribed so that we can sit back and really listen to what you're saying and make sure we have an accurate transcript of what we're hearing from you today.

Related to that, I wanted to note that today's meeting is separate from the recently closed public comment period on the petition for rulemaking on extravasation. We do have a petition for rulemaking in-house right now that we're reviewing.

And these two efforts do merge, obviously. But we wanted to get public comments outside of just the petition for rulemaking that's

requesting that certain extravasations be reported as medical events.

So that's the purpose of this meeting. It's broader than just that petition really. And it's separate from that petition.

So I will post the link to regulations.gov site - the docket for this petition for rulemaking - in the chat in just a moment, but you can go ahead and take a look.

The petition for rulemaking FRN received over 400 comments. The comment period closed on November 30th. So if you're interested in seeing what kind of comments we've received on that you can check that here. But it is separate from today's meeting.

And the last thing I'll finish with before handing it over to Lisa is we are going to have a meeting summary of today, so it will of course include the transcript of today.

We'll post it on our medical uses licensing toolkit. I'll post that link in a second. We can also email it out via our medical list server email as well.

And if you're not on our medical list server email I really encourage you to sign up for

that. Again, I'll post that in the chat. But that's a good way to get occasional emails from us on what the medical team is doing.

With that, we'll go to the next slide and I'll let Lisa take over from here.

MS. DIMMICK: Thank you, Sarah. And welcome everyone. We really appreciate you taking the time today to provide feedback to the NRC on this topic.

We're very interested in your comment on this topic.

The NRC Staff has been, sort of has been evaluating extravasation for some time, we started this evaluation a while ago and we're very interested in your feedback.

Today we'll just cover briefly what we mean by extravasation. A little bit about the 1980 rule that excluded extravasations from being reported as a misadministration, what our evaluation entails, a little bit on the congressional interests that we have had about extravasation and reporting them as medical events.

And then we have some discussion questions for you, and this is where we'll take your public comment. And we kind of have grouped them

into areas of injection, quality, monitoring, classification and reporting.

So we'll tee-up each of those discussion areas. And if you have comments and think they fit in one of those bins, if you could hold them until that portion of the meeting that would be great. And then we have some other factors and considerations that you might have comments on.

Next slide please. Okay, so a working definition of extravasation - it's the unintentional leakage of an IV infused drug into the tissue, into the surrounding tissue of a vein or artery during the administration.

Note that extravasation is not just unique to radiopharmaceuticals - that extravasation occurs with other drugs. Like chemotherapy or with contrast media. And other types of drugs.

The studies indicate that the overall extravasation rate is about .1 to 16 percent of injections. And we also know that there are many factors that contribute to why an extravasation might occur. Such as the patient's anatomy.

Could be the training and experience of the health professional administering the drug. As well as possibly the catheter size or needle size

used to make the injection.

Next slide. So, in 1980 the NRC promulgated the misadministration regulation. And this is the rule that required reporting of certain misadministrations with radiopharmaceuticals.

And in 1980 the Commission did not require that licensees report extravasations as misadministrations. During the public comment period for that 1980 rule, there was a comment or question on extravasations - were those considered misadministrations?

And at that time those comments were resolved that extravasations frequently occur, in otherwise normal intravenous or intra-arterial injections, and that they are virtually impossible to avoid and therefore the Commission did not consider extravasations to be reported as misadministrations.

And subsequently, when the NRC updated its misadministration regulation to the medical event reporting regulation in 2002, it didn't make any changes with regard to extravasation. And so therefore it would still be considered that extravasations would not trigger the medical event report criteria.

Next slide. So why now reevaluate the

1980 position?

Well, a few things. 1980 was 40 years ago and there are a number of new diagnostic radiopharmaceuticals that have been approved by the FDA. And there are a number of therapeutic radiopharmaceuticals administered intravenously then what was around back in 1980. And there are many more coming down the pike.

So it might be an opportunity to evaluate whether our regulations in the right place in regard to medical event report and extravasation.

We also have a petition for a rulemaking for extravasation. And in this petition the petitioner is requesting that extravasations that result in a local dose, a 50-rem dose to the tissue around the injection site, be reported as medical events.

We've also had congressional interest urging action on extravasation.

Next slide. So, NRC Staff has actually been evaluating extravasation for a while now. And we're trying to determine whether extravasation should be reported as medical events. And if so, what is the appropriate reporting threshold for these events.

So, Staff is basing its evaluation in a couple of areas. One, is extravasation preventable with technology, two, is extravasation a practice of medicine concern or a regulatory concern or both. And is the dose consequence significant enough to merit a change and require regulatory reporting.

Next slide. So, our next steps with regard to extravasation are, as I have mentioned, we've been evaluating extravasations and whether or not they should be reported as medical events.

Staff does plan to provide its Advisory Committee on the Medical Uses of Isotopes, or the ACMUI, with a draft of our evaluation. And a number of options, possibly, for extravasation.

We do plan to provide this information to our ACMUI in late January. The staff, at the same time, will continue and complete its technical evaluation. And we do plan that we should be completing this evaluation in late April.

And then with the petition for rulemaking for extravasation, that is on a path for in the petition process for a decision to either accept or deny that petition, would be around the month of June.

Next slide. I had mentioned that there has been congressional interest in extravasation.

The House and Senate Fiscal Year '20 appropriation bills had required NRC to provide a report to Congress on updates to injection quality monitoring classification and reporting requirements regarding extravasation.

That report to Congress was submitted March of 2020. And the ADAMS session number is ML20050W302, if you're interested to review it.

In the draft bill for the House Fiscal Year '21 appropriations does have language that would require NRC to report back to Congress on the reevaluation of nuclear medicine event reporting.

So, again, I had mentioned that there has been congressional interest. As such, this is one area that we have provided information to Congress on extravasation.

Next slide. So, we want to take your general comments on anything about extravasation. And we've kind of will structure the discussion and questions in these following topical areas.

Injection, quality, monitoring, classification of medical events, reporting of medical events and other factors and considerations.

I'm going to kind of go into each of these sections. And that's when we'll pause to take

comment.

And we'll proceed for these four areas. And as we, and if we get to the end, and we still have time, we'll continue to take your comment for as long as people want to give us comments today on extravasation.

But I thought, again, that we would bend them in areas to try to focus your comments on a few areas.

Next slide. Okay, to kind of tee-up injection quality monitoring.

The medical use policy statement, and it's published in the Federal Register, and the citation is 65 FR 47654, guides the NRC's regulation of the medical use of radionuclides as necessary to provide for the radiation safety of workers and the general public.

The NRC does encourage licensees to use quality assurance tools and available technology to ensure that the licensee delivers the administration that the position intended.

In fact, the NRC requires certain quality assurance procedures. Such as calibrating instruments used to measure patient dosages and recording of dosages administered.

But there are many procedures that the NRC does not require that licensees do for quality assurance.

Next slide. So, in the area of like injection quality measuring, I'm going to just read these questions and we'll take comment on this - you can either respond directly to these questions or provide comment on these questions or something like these.

But the question is, do you monitor for radiopharmaceutical extravasations?

And I guess if so, how, if so, why, and if so, what do you do with that information or why do you monitor at your facility for radiopharmaceutical extravasation?

And then another question is do you expect that monitoring for extravasation and reviewing the results would improve radiopharmaceutical administration techniques, and is there technology that can prevent extravasation?

And think in terms of therapeutic administrations versus diagnostic administrations, you know, we'd be interested in your thoughts in that area.

Do you believe a regulatory action

requiring monitoring and review of extravasation if appropriate?

So with that, Sarah, I'm going to turn it over to you to see if we've received any questions or comments. If not, then we'll continue on and just go to the next topical area.

MS. LOPAS: Yes. So we did have somebody pointing out that they needed further instruction on how to raise their hands.

MS. DIMMICK: Okay.

MS. LOPAS: So, if you're on the WebEx, if you look on your lower right-hand corner, there should be two icons, participants and chat. If you click on participants, it should bring up a list of, probably just the panelists, maybe, for you.

There is a little hand on the right side there of that participants panel. If you click on that hand it will say raise hand. And it should show up, your hand should kind of show up next to your name. So you can raise and lower your hand that way.

So when you raise your hand, that way Kellee can see that your hand is raised and she can then unmute you. And then when you're done speaking and you're all set, you can lower your hand again, and that way takes it off the list for Kellee to know

that she's got you.

So right now we're looking for any kind of feedback, or any general comments right now to get us kicked off on this first topic here on injection quality monitoring.

And as a reminder, send in your chats too, to me. Send your chats to me by sending them to all panelists, and then I'll read them aloud. And that way our transcriptionist can get an accurate transcript here. Our court reporter, I mean.

So, I do have the first question here, and it's related to the 400 comments that we received. So, this is from Ralph Lieto. And he says, ''Do you expect to review/evaluate, more than 400 comments by your assessment in January?''

MS. DIMMICK: I'll take that. So those comments are received as far, for the petition for rulemaking.

So, the rulemaking group, the petition review working group, will be working through those comments. Again, as I had mentioned, Staff was evaluating extravasation, and then a petition came in.

And then we all, we had planned to have this meeting earlier in the summer. And actually,

it was being planned before we had received the petition.

So, I'm just trying to highlight that staff was initiating, or evaluating, extravasation. So this, what we're going to have prepared by January isn't necessarily responding to the petition, it's Staff's technical evaluation.

So that's what we're having, planning to have ready, by January. It's just, our assessment of extravasation, the medical team's assessment of extravasation and a recommendation for options, and what we see is options for extravasation.

And it will probably marry at some point with the rulemaking group in that petition. But I just wanted to point out that the comments are being evaluating through the petition rulemaking group.

And we are coordinating, but this is a separate evaluation than the comments being received from the petition.

MS. LOPAS: And, Ralph, we are very aware of all those comments. We have access to all of them. We've been coordinating with the petition group, so yes.

I mean, that's what the NRC does, we go through comments and we review them quickly because

that's kind of, that's how we operate here with public participation.

So here's our second comment here. This is from Brian Goldstein.

''Thank you for providing this additional hearing. I previously submitted a written comment regarding this unique opportunity for the NRC to make care safer for a very large number of already vulnerable people.

Now, having reviewed many of the other submitted comments, I wish to offer this comment. Yes, monitoring, combined with well-established quality improvement processes, will improve administration techniques.

Yes, there is technology that can prevent extravasation, when combined with simple QI. Yes, I believe that regulatory action requiring monitoring and review is appropriate, and also ethical. Yes.''

All right, so thank you, Brian, for that comment.

We have the next comment here from Matthew Williams. ''There is no real technology that will prevent these from occurring. Monitoring may allow us to start corrective actions earlier, but no more than an hour.

The scan will clearly show if an extravasation occurred. Having monitoring conducted will not reduce the rate; again, just likely allow us to address them prior to the scan.''

All right. I'm going to see, Kellee, do we have any hand raised because I do have Tina Buehner trying to raise her hand but she's not sure if it's working. So I'm not sure if you're able to unmute Tina without her raising her hand.

MS. JAMERSON: We have, Paul Wallner is first -

MS. LOPAS: All right. Go ahead, Paul. Just make sure you say your name clearly for the court reporter.

DR. WALLNER: Thank you. It's Dr. Paul Wallner, W-A-L-L-N-E-R. I'm a physician, radiation oncologist. I'm also board certified separately on diagnostic radiology and nuclear medicine.

I'll comment on all four of these bullet points. I think one of the issues that petitioner and NRC must keep in mind, is the fact that what you've seen are anecdotal reports; suggest very clearly how rare these instances are.

And in fact, even among the anecdotal reports, the incidence of significant injury to

patients is even more rare. And essentially so rare that it is reportable.

Monitoring of extravasation is done, if the extravasate is felt to be significant. And that's so rarely the case because in most of these radiopharmaceuticals, the volume is very small and the extravasate is noticed instantly.

If you expect monitoring for extravasation in reviewing the results to improve administration techniques, no. We do monitor, and techniques are extremely careful at this point in time.

Is there a technology that can prevent extravasation? As a physician whose been in practice for 48 years, and in nuclear medicine and diagnostic radiology and radiation oncology with all of these agents, I can tell you, absolutely, there is only a single technology. And that's to put these through an indwelling central catheter, a central line into a major vessel.

And the physicians who manage those, who are typically surgeons or intensivists, absolutely do not want those central lines to be used for other than nutrient or lifesaving techniques. So, there effectively is no technology other than care.

And regulatory action requiring monitoring will not change anything. This is still extremely rare. There is no evidence of significant harm to patients. There is no evidence that additional monitoring would improve patient care one iota. Thank you.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Yes, thank you, Dr. Wallner. Okay, Kellee, who is up next? Or if we can try to grab Tina?

MS. JAMERSON: What's the last name?

MS. LOPAS: It's, B-U-E-H-N-E-R.

MS. JAMERSON: Tina, your line is open -

DR. BUEHNER: Hi. Can you hear me?

MS. LOPAS: Yes.

DR. BUEHNER: Okay, thanks. Good afternoon. I am Tina Buehner. I am a health physicist at Rush University Medical Center in Chicago, Illinois. And I'm also the president of the Society of Nuclear Medicine and Technologist. Molecular Imaging and Technologist Section.

And I'd like to thank the NRC for allowing me the opportunity to speak on the call today. And hopefully I'll be able to touch four of these points.

The SNMMI is a not-for-profit international organization of over 16,000 professional members. Including physicians, scientists and technologists. And it is one that is dedicated to the advancement and advocacy of nuclear medicine and molecular imaging.

Before entering the world of health physics and radiation safety, I previously worked as a nuclear medicine technologist for 18 years. During the 18 years of clinical practice I have personally administered thousands of diagnostic radiopharmaceutical injections.

Some of those injections, particularly as an early career and novice technologist, have resulted in a full or partial extravasation of the dose. This was unfortunate because those patients either had to receive another injection or some had to reschedule their exam as a result of that.

Extravasations are undesirable outcomes of injections. And they have a significant detrimental effect on image quality as well as negatively impacting the patient's overall experience and their satisfaction of care that they're receiving.

Nobody wants an extravasation to occur.

Not the patient receiving the injection nor the administrating technologist whose skills are being put in the spotlight, nor the physician interpreting the study.

And there are a plethora of factors that can help or hinder successful venipuncture. We have better technology that can help us. And we know how to monitor for these things visually.

However, regardless of the extra steps the technologist may take to prepare, even for the most difficult of injections, they can still occur. There is simply unwanted undesirable outcomes in the practice of medicine.

That being said, we know that nuclear medicine and molecular imagining plays an integral role in oncology. Including the diagnosis and management of many different diseases.

And often times, as part of the monitoring for disease response, progression or evaluating chemotoxicity on the heart, these patients will undergo routine exams in nuclear medicine at frequent intervals.

Sometimes they are seen at three or six month intervals; and that could last for years. And as technologists, we often see patients routinely on

a frequently basis.

I, personally, having spent the first 14 years of my career at the same large well respected academic medical institution in downtown Chicago, have seen many patients that I cared for routinely throughout those years. And I was never aware of any immediate or deterministic effects as a result of a prior diagnostic radiopharmaceutical extravasation. Whether done by myself or one of my almost 20 other technologist colleagues.

Therefore, I've seen no evidence in practice that the diagnostic radiopharmaceutical extravasations can cause harm to the patients. And that being said, and as a representative of other professional organizations that promotes safety and quality and practice, I am much more concerned in ensuring that nuclear medicine technologist fully understand the gravity that the extravasations can have in quality and diagnostic accuracy of patient studies.

Particularly in quantitative analysis such as standard uptake value calculations in PET imaging. And I believe the diagnostic accuracy is much more of a pressing concern than radiopharmaceutical harm.

As such, and in response to the petition that is being currently proposed the technologist section of the SNMMI is addressing extravasations as a quality initiative this year and is focused on reiterating the importance of quality injections, revisiting best practices in radiopharmaceutical administrations. And then discussing technical considerations for optimizing venipuncture procedures.

But ultimately, we believe that this is best managed, you know, on an individual patient basis, provide personalized care. And at the institutional level, by the authorized user.

So we don't believe that regulatory action requiring monitoring is appropriate at this time. We support the ACMUI's recommendations and do not believe any further rulemaking is going to help this.

So, again, thank you for allowing me to speak.

MS. DIMMICK: Thank you for the comments.

MS. LOPAS: Yes, thank you, Tina. So, Kellee, just let me double check, are there any other hands raised before I get into some of these chat comments?

MS. JAMERSON: Yes. We have two more.

MS. LOPAS: Okay.

MS. JAMERSON: First, Terry Wong.

DR. WONG: So thank you very much for having this conference and review. I am Terry Wong and I am a physician and have practiced nuclear medicine for over 20 years and I concur with the previous speakers.

In my experience extravasation of especially radio tracers has never caused a medical problem, and so I do not believe it should be regulated.

I think the fact that since 1980 we had that rule and if you look historically I think that actually supports the safety of our intravenous radio tracer injections.

I also want to mention that I was involved with the work with the person who authored the petition, so I participated in that work, and that showed basically studied extravasations, the incidents, and the effect of potentially intervening and improving that.

So I think it's a value for improved technical improvement, but that doesn't make it necessary and I don't believe that it's necessary for

it to be further regulated.

I think, also, we have to be clear about the difference between monitoring and prevention. So this instrumentation will allow monitoring, but it doesn't prevent.

And like the previous speaker mentioned, there is no way to prevent really and so that distinction I think is really important to make between the monitoring and prevention. So being able to monitor will not necessarily in itself reduce that.

So I just wanted to say I do support the consensus of the SNMMI and other organizations, ACNM and ASNC, in building that extravasations are a practice of medicine issue.

There is experience in place for extravasations. We managed it for chemotherapy, for IV contrast injections for CT scans, and managed those with organized and, you know, well-defined procedures.

I also feel that the rulemaking, if it's a rulemaking, would also, you know, cause unnecessary and regulatory reporting requirements and will divert resources away from safety issues that may be more important.

So I also believe that it wouldn't in the

end really have an impact or improve patient safety, which would be the original intent. So thanks a lot, again.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Kellee, let's go to one more audio comment and then I do have a number of chats that I want to get to, but a reminder that folks can do both, they can raise their hand like they have been doing or go ahead and send a chat and I will read it aloud.

MS. JAMERSON: Okay. Next is Pat Zanzonico.

DR. ZANZONICO: Yes. Hello, everyone. Thank you for the opportunity to comment. In addition to echoing all of the comments of the previous speakers about the infrequency and lack of clinical consequences of radiopharmaceutical extravasations I wanted to emphasize the distinction between regulatory oversight and practice of medicine.

As at least one of the previous speakers mentioned, the major impact of an extravasation is to compromise the diagnostic quality of a scan, especially a quantitative scan.

We should all recognize that is a component of practice of medicine, that that is beyond the scope and responsibility of regulators and regulatory action.

In that vein, therefore, if this petition were accepted and extravasations were in fact made a reportable event it would be a slippery slope, so to speak, in terms of regulators intervening in medical practice in terms of adjudicating a quality of scans and measures by practitioners to improve quality of scans.

So I think besides all of the other compelling reasons for rejecting this petition one that is certainly chilling is the potential over-regulation and intervention of regulators on medical practice. Thank you.

MS. DIMMICK: Okay. Thank you, Pat.

MS. LOPAS: Okay. So go ahead and hit your raise hand icon to get in line to speak a comment, but I am going to read a couple of these chat comments as they are coming in.

So the next comment is from Kendall Berry. "We have started to monitor for extravasations at the conclusion of Lutathera infusions.

We are measuring exposure rates at the IV site and 30 centimeters from the IV site using an ion chamber. Very new change in process. Hope is to allow for quick initiation of actions to minimize potential skin dose."

All right. And then our next question we have here is from Richard Wahl. So he says, "You mentioned congressional interest in the topic of extravasations. Could you clarify if specific legislators were particularly interested in this topic, i.e. name and state?"

Lisa, is that something that you could address?

MS. DIMMICK: So we have the congressional report that is publicly available and then we received a few letters. I think we can share those. They are publicly available, so we could share those letters in the chat.

I think that will be fine to do for the link so you can see the letters that were sent in.

MS. LOPAS: Yes, let me work on that. I am going to -- I do have a number of ML numbers. I just need to make sure that the links that I am providing are the public links.

So give me a little bit of time,

everybody, on these publicly available letters and I will get them in the chat for you to read.

MS. DIMMICK: Okay.

MS. LOPAS: Okay. And these letters were from North Carolina Senator Tillis and Representatives Price, Holding, and Butterfield. So, these are all legislators from North Carolina. So just give me a few minutes and I'll get the links to those letters.

There is a -- I believe Senator Tillis submitted a comment on the petition as well, so I could try to find that comment, the link to that comment, as well.

Let's see. So our next comment is, this is from Jeremy Iman, "We do not monitor for radiopharmaceutical extravasation. Requiring that for every patient would add significant time to the patient imaging. For therapy it would mean finding camera time, which is not normally included for therapy patients."

MS. DIMMICK: Okay.

MS. LOPAS: And then we have a note from Terry Wong. Terry Wong says he is following up to "Note that monitoring for extravasation is different from prevention." which I believe he expanded on that

in his earlier comment.

And then another follow-up from Kendall Berry, "I believe that in routine care of the patient therapeutic extravasations will be addressed by the medical and radiation safety staff to minimize effects on the patient regardless of regulatory action."

Okay. And another follow-up from Jeremy Iman, "I also do not see how it would improve administration techniques. IV administration is a common technique and part of the scope of practice for nuclear medicine techs. It is taught in all nuclear medicine schools."

And then we have a question here from Andrew Zimnoch, which, Lisa, maybe you can answer. "Is the evaluation of extravasation considering only diagnostic administrations or also therapeutic?"

MS. DIMMICK: So we'll continue on with that as part of our discussion in the next areas. Right now, I mean that's a consideration, should the reporting be inclusive of diagnostic and therapeutic if there was a certain dose threshold exceeded or should the extravasation reporting be limited to therapeutic radiopharmaceutical injections if they were extravasated.

So we're evaluating just extravasations and it could be diagnostic and therapeutic, both or one or the other.

MS. LOPAS: Okay. And, Kellee, can I ask you really quick, I know this is kind of a pain, do you mind going back to that slide up front that shows where folks click to make a comment or to click on there to raise their hand. Okay, yes.

We're getting a couple questions on where to raise your hand. So it is a little bit tricky. So you have to make sure that you have the participant's panel open, so not just the chat, but also click on the participant's icon next to the chat there on the lower right-hand side.

It's small, but you see where I have the number three, click the small hand icon to raise or lower your hand. You have to just click on that once and that will raise your hand and then when you are done speaking you click on it again to un-raise it.

So hopefully that helps in terms of getting people in line to speak. All right, Kellee, sorry, you can head back to that other slide. Let me just see where we are in terms of these chats.

Okay. We've got a lot of chats here, so I am going to get through them.

MS. DIMMICK: Yes, so if we could, Sarah, we'll try to get through these because we have to mindful of our time, too, to get to the other ones, but they will be, either we'll read them into the transcript at some point or we'll have them in the transcript.

MS. LOPAS: Yes.

MS. DIMMICK: But we'll have a copy of the chat comments, so if we aren't able to get to all of the chats to read them out loud we will have a copy of the chat so NRC staff will have them anyway.

MS. LOPAS: Yes. And let me just remind everybody that submitting chats, please, please, please, try to select in the drop-down menu, there should be an option that says "all panelists" so that you are submitting your chat to all of the NRC panelists.

Because if you don't select that it just goes to Kellee and she is getting inundated and only Kellee can see them so then she has to copy and paste them to us, so that's something that we'll try to fix for future meetings.

Let's see. We have a chat from Scott Fuller that says "I am also unfamiliar with technology to prevent extravasations. There seems to be

different opinions from other commenters." Okay, so that was from Scott Fuller; that comment.

Michael Hall comments, "We monitor for radiopharmaceutical extravasation through routine imaging. If there is pooling it will be found on the images."

From Les Morrison, "I am a radiation safety officer. I have talked to several radiologists on this type of topic. No one seems to be concerned when this happens with contrast or other medications. Why should this be of concern when it is a common issue?" Okay.

And then we have another comment from, and I am going to not be able to say your name correctly, Lori, Lori Kaczmarek. I hope I got it right. Lori says, "If the volume of infusate is small, how is it observed?"

I think that was a, she had kind of follow-up comment on a question on a comment that somebody else, I think Dr. Wallner made.

And then from Michael Hall, "What was the ACMUI's opinion on the inclusion of extravasations as medical events? They met recently." Lisa, can you address that?

MS. DIMMICK: So let's share that at the

end.

MS. LOPAS: Okay.

MS. DIMMICK: We can maybe share the link to their report and we can review ACMUI's report at the end if there is time. But we can always, we can share the link so that people can read that.

MS. LOPAS: Yes. I just shared the link. And, I'm sorry, folks, I will get those congressional letters posted, too. It's just I might have to do it a little bit towards the end, okay.

Let me keep scrolling through these, Lisa. I will take a look at the rest of the chats if you want to go to the next one.

MS. DIMMICK: Yes, let's continue.

MS. LOPAS: Okay.

MS. DIMMICK: Okay. So next slide, Kellee. Okay, so classification. So currently the NRC excludes extravasation of radiopharmaceuticals from its medical event reporting regulations.

Medical events may not necessarily result in harm to the patient, but they can indicate a potential problem in the medical facility's use of radioactive materials and administration as directed by the physician.

Next slide. So if we were to require

reporting of extravasations that meet a medical event reporting criteria should a distinction be made between reporting extravasation of diagnostic and therapeutic radiopharmaceuticals?

Should a different dose threshold be developed for extravasation or should there be certain caveats like with Yttrium-90 microspheres?

Let me give you an example. So if you are familiar with Yttrium-90 microspheres and that administration and you know that microspheres fall under NRC's 10 CFR Part 35.1000.

Anyway, so with microspheres in one of the medical event reporting conditions or criteria it's a dose to the skin or an organ or tissue other than the treatment site that exceeds by 50 rem to an organ or tissue and 50 percent or more of the dose expected from the administration defined in the written directive, but it excludes shunting.

So if shunting was accounted for prior to the evaluation and shunting occurs and causes that 50 rem dose and 50 percent or more of the dose from the expected administration then that's like the caveat that I am talking about.

So is there something with regard to radiopharmaceutical administrations and

extravasation that might need to be considered with regard to developing a criteria for classifying extravasation as medical events.

I am just giving an example of something exceptional that should be considered if they were reported.

So if extravasations were classified as medical events how would you make the dose estimation for an extravasation event if the criteria is a dose-based criteria?

So just a couple of things to think about with regard to classifying medical events, or classifying extravasations as medical events. So any thoughts or comments in the area of classification?

MS. LOPAS: Okay, Lisa, I am going through quite a number of chats.

MS. DIMMICK: Okay. Well, we can continue with the chats while we have the screen up.

MS. LOPAS: And let me just make a note, one of my colleagues here at the NRC let me know that for those of you that are using the web browser of WebEx that my instructions on how to raise your hand might not make sense.

So if you are on your web browser there is a little black circle in the center of your screen

where all the other circles are. I'm trying to describe it. It's three dots kind of like in a row - vertical dots.

If you click on that the top option will be raise your hand. So that's maybe why some of you aren't able to see the raise your hand option, but click on the little dots on the middle of your screen, that black icon, and hopefully that will help you raise your hand. I apologize for that.

Alright, let's see. Lisa, I am going to start with one of these. I will go back when we have time, right, but I am going to start here with a comment from Michael Baxter I think maybe related to classification.

Michael Baxter says "Therapeutic quantities of radiopharmaceuticals can deliver doses that are hazardous but such an event is already considered a misadministration reportable per the current rules of 10 CFR 35.3045.

Therefore, we do not support the need of additional rulemaking for reporting nuclear medicine injection extravasations as medical events.

Accordingly, we do not see value in additional NRC rulemaking for reporting nuclear medicine injection extravasations as medical events.

Such matters are best managed locally at an institutional/hospital level of the facility practice as a quality improvement process." Okay, that is one comment.

Then here is another comment on this. This is from Max Amurao. "10 CFR 35.3045 establishes the report and notification of a medical event. An extravasation appears to be encompassed by a dose that differs from a prescribed dose.

As such, there does not appear to be a need for regulatory action requiring monitoring and review of extravasation."

So, Lisa, I don't know if you wanted to comment on this because both of those comments seem to think that extravasations are already in some way captured in our current reporting requirements, but that's not quite, that's not right.

MS. DIMMICK: Yes. The reporting criteria are conditional criteria. So there is a dose criteria, but then there is something else that has to happen as well.

And there is basically three criteria, well, actually there is criteria and then there is criteria for permanent implant brachytherapy, but without trying to really dissect them the Criterion

1 that's the dose -- So with an extravasation what you possibly have could be an underdose to your target area and that's how Criterion 1 would apply.

It does not apply to the dose at the extravasated site. Then the second criteria, again it's the 50 rem and five rem whole body, plus there has to be an error like the wrong patient, the wrong route, the wrong drug.

So, you know, the question is would extravasation be considered the wrong route of administration. Well, that's not what you intended to -- I mean unless you purposely did an interstitial injection as opposed to giving an IV injection, I mean that's where wrong route could maybe play into this, but, again, the regulation wasn't crafted with thinking in terms of extravasation.

And then the other criteria is similar to the Yttrium-90, well, the one that I read, the 50 rem, to another site than what was intended. This one does require a written directive, so this is for administrations that require a written directive.

But digging down into this criteria, it's a little odd, too, if extravasation truly fits in there as well. So these are things that we are doing to evaluate because we need to be able to clearly

show that extravasation can or can't fit in these criteria.

The way they are crafted it's a little bit of a challenge, it's a stretch, because it wasn't intended that, I mean, again, when the 2002 rule for medical events reporting was crafted, again, we had the 1980 misadministration statements of consideration that like extravasations were, you couldn't avoid them.

MS. LOPAS: Okay. Thank you, Lisa.

MS. DIMMICK: Mm-hmm.

MS. LOPAS: So Kellee let me know there is a number of hands raised.

MS. DIMMICK: Okay.

MS. LOPAS: So let's catch up with all the hands raised as I try to kind of keep going through the comments, because I know we have a number of comments that I got through chat.

So, Kellee, let's go ahead and just start with the hands.

MS. JAMERSON: Okay. Next is Dr. Carol Marcus.

DR. MARCUS: Hi, there. Can you hear me?

MS. LOPAS: Yes.

DR. MARCUS: Okay, good. I agree with what the previous physicians have said. I am not going to repeat a lot of it. I would like to make a couple of other points.

Basically, this is a non-issue and I don't think the NRC should be involved with extravasation at all. But as a person who has written a number of petitions to the NRC I find Lucerno's petition curiously detailed, containing references and information most petitioners would not know about. It has the smell of collaboration with someone at the NRC.

I would recommend an IG investigation to see if someone in the medical section has collaborated with Lucerno in the preparation of this petition and maybe collaborated with people in Congress to get congressional interest revved up on this. I really don't buy the idea this was all spontaneous.

I mean we have been using radiopharmaceuticals mainly since the Second World War. A few hundred million doses have been injected and it's never been an issue and it isn't an issue now. There is something really that smells about this whole rulemaking as far as I am concerned.

Another point that I would like to make

is that one of the reasons for a partial extravasation or some extravasation is the patient themselves. The patient may suddenly lurch and move and it's not the technologist's fault or the physician's fault, it's something the patient does.

Now this is not too much of a problem with adults, but with babies and young children it certainly can be a problem. In the hospital I worked in there were teams of people that put in IVs for babies and children and the other physicians and technologists were not allowed to do IVs.

They had to use the IVs put in by these specialized teams. Well, if somebody on this specialized team didn't do a good job whose fault is it?

It's not the nuclear medicine physician. It's not the nuclear medicine technologist. It's a non-nuclear person and, you know, these teams do the best they can.

I am really concerned that pediatric nuclear medicine is going to be in real trouble if you make a disgusting regulation that is going to demand reporting of partial extravasations.

I also think it may happen that physicians will not want to do therapy because they

are afraid. I am afraid that people will not go into nuclear medicine technology, they will become x-ray techs instead, because of the overbearing regulatory actions of the NRC. So I really, really think you should drop this whole rulemaking.

I would also like to point out that in external beam radiation therapy it is not at all unusual to have what's called, well, they're wet burns, wet desquamations.

You get skin burns so bad that the whole skin rots away, you know. It could be a pretty large area. It takes weeks and weeks for these things to start to heal over. It takes years for it to finish healing and the scars to decrease.

These things happen every day all over the nation. It's one of the side effects of radiation therapy. Nobody reports them. You just do the best you can with various burn ointments and treatments for the patient.

This is a far, far bigger problem than anything in nuclear medicine and, still, it's taken care of at the local level by way of the department and it's handled perfectly well.

So I really would hope the NRC would get rid of this evil rulemaking. Thank you.

MS. DIMMICK: Thank you for your comments, Dr. Marcus.

MR. EINBERG: Yes, this is Chris Einberg. I am the Branch Chief of the Medical Safety Events Assessment Branch. Yes, thank you, Dr. Marcus, for your comments.

I just did want to respond to one of the issues you raised regarding the appearance of collaboration with the Petitioner. You've communicated that to us in a previous correspondence and that was referred to the OIG.

So we take these types of things very seriously and it will be investigated by the OIG, but I can assure you that there is no collaboration but the OIG will investigate.

MS. LOPAS: Alright. Thank you, Chris. I do have a request from some of the commenters that it would be helpful if everybody identifies yourself and if applicable your affiliations.

That would be helpful so we know, you know, who folks are affiliated with as they are commenting. That would be very helpful. So that was one request I got.

So, Kellee, let's go to the next raised hand.

MS. JAMERSON: Next is Robert Schleipman.

DR. SCHLEIPMAN: Good afternoon. Can you hear me?

MS. DIMMICK: Yes, Dr. Schleipman.

DR. SCHLEIPMAN: Oh, great. So I'm Robert Schleipman. I'm affiliated with Mass General Brigham in Boston. I'm a member of the ACMUI though do not serve on the Infiltrations Medical Event Reporting Subcommittee.

And I'd like to share a few comments. These do touch tangentially on the petition for rulemaking but also address the slides. So a thoughtful and experienced radiation oncologist once mentioned at a Radiation Safety Committee meeting that if you were reporting mistakes, you're not doing enough cases.

And I would say that appalled was too strong a word, though I was initially taken aback by this, though subsequent work in risk management and patient safety convince me he was not far off the mark. In fact, the prestigious National Institutes of Medicine and their landmark To Err is Human report illuminated the problem of widespread medical errors, much of which could be preventable. So then a problematic administration of radioactive material

while defined as of patient origin could possibly arise from medical error, say, perhaps the sleep deprived staff member who just finished multiple shifts or some other thing.

But an important thing to remember is that that same National Institute's report ushered in a number of quality improvement processes and further sparked the evolution of safety culture, of examining near misses, and transparency in reporting. Hospitals don't just report to NRC inspectors or state radiation control bureaus. They're routinely audited for compliance by the Centers for Medicare and Medicaid Services, the FDA and their Clinical Laboratory Improvement Act, the Joint Commission and so on.

And in the case of the Joint Commission, the environment of care is routinely evaluated as are the documented training, continuing education; the competencies of staff. And those demonstrated competencies include handling of IV lines, administration of pharmaceuticals, medication management and so on. There exists multiple mechanisms to evaluate and promote the safe administration of radioactive materials to patients and research subjects within the broader scope and

practice of medicine.

Under these initiatives and surveillance, inadequate injection techniques by staff or larger process problems would be and are investigated and remediated. And you can be certain that if patients routinely return from nuclear medicine to nursing floors with compromised IV lines or painful extravasations, there would follow incident reporting, root cause analyses, and corrective and preventative action plans. Thus, I believe the ACMUI and subcommittee understood that the majority of extravasations are likely to occur from patient movement, vascular access problems and so forth and not practitioner error and that revising NRC rules to require the identification, evaluation, and dosimetry of every radionuclide extravasation, particularly of diagnostic radiopharmaceuticals which pose little adverse consequence as compared to high dose therapeutic beta emitters is an exceedingly blunt instrument that would impose significant burdens to healthcare institutions which already have varied processes in place to minimize extravasations and/or clinical practice issues.

The oft quoted systematic literature review by van Pol provides evidence of minimal adverse

effects from diagnostic administrations -- or extravasations. In a more comprehensive perspective study by Silverstein of 11 academic centers submitting characteristics of their radiopharmaceutical administrations and adverse events over a five-year period evaluated over one million radiopharmaceutical administrations, including over 200,000 diagnostic PET studies, over 800,000 diagnostic non-PET studies, and over 13,000 therapeutic procedures. This report concluded that the incidents of radiopharmaceutical adverse events was 2.1 for every 100,000 administrations.

The petitioners raise a good argument for monitoring and preventing extravasations. However, the petition seems in places to conflate diagnostic radiopharmaceutical administrations with therapeutic ones and the untoward effects of vesicants used in chemotherapy. Adverse effects of severe tissue damage and radionecrosis are supported by citations referencing those very few incidences of extravasations of therapeutic radiopharmaceutics and just further reinforces the rationale for comprehensive training and experience requirements of authorized users.

In contrast in the petition, the cited

case report regarding diagnostic radiopharmaceutical extravasation notes patients' absence of cooperation during injections, spontaneous resolution of lesions without complications and concludes that patients and physicians must be reassured because of the non-vesicant property of technetium. And recovery of this entity is spontaneous and no treatment is needed. That the petitioners have developed a device to assist in uncovering and monitoring perivascular injections is a very welcome development as it could be employed as a quality improvement and educational tool.

And in their publication by Wong and others, it underscores this point and clarifies that nuclear medicine infiltration rates could be reduced and sustained through quality improvement. I'd like to thank Dr. Wong for his forthrightness and clarifications in this. I would conclude that there's ample peer reviewed evidence of very few harmful consequences from extravasations of diagnostic radiopharmaceuticals and that proposed rulemaking is an inappropriate and unnecessary instrument given quality improvement opportunities of practices under the broader scope of medicine. Thank you.

MS. DIMMICK: Thank you, Dr. Schleipman.

MS. LOPAS: Okay. Kellee, next commenter, please raise their hand. And you're muted, Kellee, if you're speaking.

MS. JAMERSON: Next is Drew Garner.

MS. LOPAS: Hi, Drew. Are you there? Drew, you may have been -- you may -- I don't know if you are muted yourself. Drew?

(No audible response.)

MS. LOPAS: All right. Kellee, maybe we'll come back to Drew. Is there another person after Drew?

MS. JAMERSON: Next is Valerie.

MS. LOPAS: Valerie, are you there? And a reminder for everybody to please provide their full name and your affiliation if you have one.

DR. JEWELLS: Hello. Thank you very much. I'm Valerie Jewells. I'm one of the neuroradiologists at the University of North Carolina. I practiced for six years in private practice administering and reading nuclear medicine procedures. Although I have not done that in the last several years, I am the quality and safety officer for the University of North Carolina.

So the particular vendor who is requesting that we do monitoring of all nuclear

medicine procedures did indeed speak with me quite some time ago about their device. Regardless of whether their device is appropriate and accurate with regard to determining extravasations, as many other physicians and technologists have previously stated, there is a very low risk for these procedures. There is very, very low probability of untoward consequences, unlike CT extravasations where there are large contrast loads which can result in skin sloughing and compartment syndrome.

I also want everyone to be aware that this particular company when they approached us with their device wanted to collect information, i.e., patient names, patient medical record numbers, dates of birth, and other important medical identifiers which are not allowed. I then referred them to the IRB at our institution who then told them just as I did that that was not an appropriate thing for their company to be done. The only reason that somebody would want to collect this information even though they're trying to tell us that it is solely so that they can determine the utility of their equipment is to sell the information for profit.

I was very much opposed to this and therefore was not interested in continuing any

further communications with this company. So I wanted you all to be aware. Thank you very much.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Okay. I just want to make a note that some people have had issues with that link I provided to Senator Tillis' comment. I'm going to have to -- what I'm going to have to do is when I send out the meeting summary for this meeting, I will ensure that all congressional correspondence that's publicly available is in our meeting summary because I'm having some issues finding -- having to look up all the incoming letters. I have all of our outgoing letters, but I know you all want to read the incoming letters from the legislators.

So I give you my word that our meeting summary will include the links to those letters as publicly available. Okay. Kellee, I'm sorry about that. Next hand raised?

MS. JAMERSON: Next is Zoubir Ouhib.

DR. OUHIB: Yes, can you hear me?

MS. LOPAS: Yes.

MS. DIMMICK: We can.

DR. OUHIB: Okay, great. Thank you. My name is Zoubir Ouhib. Let me make sure I disclose

that I am a member of ACMUI. However, I was not part of that subcommittee.

I think a lot of people have mentioned what I'm about to say is that we need to look at the big picture regarding this issue and to be very careful on the impact of any additional rules. This could potentially -- if implemented, could have a negative impact. And I think authorized users, like other people have mentioned it, might very well be very concerned just as was the case of LDR prostate brachytherapy.

People all of a sudden decided, no, I am not going to perform this and here's why. And it is a headache if you talk to the institution and all that to deal with the medical event issue and all the paperwork associated with it, the interviews. But more importantly, this is a new patient. How do you explain this and so on and so forth?

So I think we need to be very, very careful about that. Fewer and fewer people might be interested in performing this procedure because simply there's that possibility of having extravasation. And therefore, what is going to happen after that?

And as other people have mentioned it,

this is not, per se, a serious harm. And I think the last person that spoke sort of let me believe that there was a motive. It is not the desire of having two new rules to basically protect patients. But there was another motive outside of this, and that's a concern.

Let me just add to this as others have commented, including Dr. Wallner. We need to focus more on the need for better training, education, and a QM program to make sure that is constantly being looked at and reevaluated to improve these injections and perhaps minimize the extravasation and then create a little more awareness about this. Thank you.

MS. DIMMICK: Okay. Thank you, Zoubir. Kellee and Sarah, if we have another comment, we can take that now. And then we'll move on to the next section. And again, we'll try to get through our sections and then continue answering or taking comment as we --

MS. LOPAS: Yeah, we can --

MS. DIMMICK: -- move forward.

MS. LOPAS: We can move on to the next set of questions. And then I do think, Lisa, we will have time since we're going until 4:00 for me to be

able to --

MS. DIMMICK: Okay.

MS. LOPAS: -- go through all the comments, so --

MS. DIMMICK: Okay. All right. Next slide, Kellee. Okay. The -- kind of, like, the next area centers on reporting. So the NRC tracks and trends medical events, and the NRC may issue generic communications to share information about events with licensees. Some recent examples of information notices that were issued are the four listed here.

There was this Patient Skin Contamination Events with I-131 MIBG was just a one case situation. And again, we share this information so that licensees are aware of other problems and maybe can evaluate their own programs to see if there's something that they can do to maybe prevent this similar situation from occurring. The other -- another one, Methods to Prevent Medical Events, this was basically the work of the NRC's ACMUI where they made a number of recommendations on preventing medical events.

Then there was the strontium-rubidium recent generator elution events, that information notice, and then one on yttrium-90 medical events. So again, this is what we do with the information

that we get from reported events. Because licensees are not required to report extravasations to the NRC, the extravasation events are not recorded in the NRC's Nuclear Material Events Database or NMED. Next slide.

However, we are aware that therapeutic extravasations maybe resulting in some medical follow-up do happen. There are three events listed here on the slide, one involving lutetium-177 resulting in a dose of 8 +/- 4 Gray, extravasation of iodine-131 MIBG, an estimated dose of 12-16 Gray, and then one of yttrium-90, this was actually Zevalin, resulting in an estimated dose of 50 Gray to the treatment site. I don't believe any of these three occurred in the U.S., but they're described in the source that I provided here on the slide.

But it's just to illustrate that extravasations of therapeutic radiopharmaceuticals do happen and infrequently. But there might be cause for follow-up on these patients. Next slide. So those events, if they occurred in the U.S., they might get reported because one or two of them might've been significant enough where the licensee thought they needed to report it. But it technically doesn't fit under the current paradigm for medical event

reporting.

The events on the previous slide do show that there are risks of tissue reactions in patients from extravasation during therapeutic injections involving beta emitters. And then the reported doses on the previous slide would trigger medical event reporting criteria for other medical use situations. So for the other medical modalities, if there was an error or an event or a dose took another site in exceeding those limits that were -- or those doses on the previous slide, they would trigger the medical event reporting.

So this is sort of rhetorical. But the question is for NRC is, why report one type of dose situation and not the other that might occur from extravasation? So that's an area that we're thinking about or trying to understand where in this situation with these therapeutic radiopharmaceuticals. Next slide.

So here's some questions for thought. What would be the burden or unintended consequences of medical event reporting of extravasation on medical use licensees and the nationwide use of radiopharmaceuticals? What would be the benefit of reporting extravasations? If we were to require that

licensees report extravasations as medical events, what reporting criteria should be used to enable the regulator to identify problems, monitor trends, and ensure that licensees take corrective actions?

One of the reporting requirements in the regulations is to determine why the event occurred. So when you report to the NRC, that's one of the required items that you document. Why did the event occur? How would licensees make the determination of how the extravasation occurred? Just some things to think about. So any comments on the area of reporting?

MS. LOPAS: Okay. And Lisa, we have our first comment from Dr. Wallner. He said, ''The reporting citations are not open source or available for peer review and should not be considered as valid citations for this discussion.'' So is he referring to the other examples that you posted on that slide? Is that --

MS. DIMMICK: I guess I was just illustrating that there were extravasations and those were -- it was -- and in those extravasations that there was a dose known and just to document that extravasation does occur. And it may be with radiopharmaceutical administrations that's what the

reported dose was. It was just to illustrate that extravasation does occur -- I mean, of therapeutic radiopharmaceuticals. And those are the types of doses that some people have reported.

MS. LOPAS: Okay. Let me read a couple of comments here that have come, and we will get to everybody's chat comments. So I assure you that. So this one is from Susan Slane.

She says, ''I'm a retired Quality/Compliance VP for a large medical device company. Our focus was always continuous improvement with development and manufacturing of devices. A 40-year pass for infiltration exposure that could be higher than a dose now requiring reporting for a spill of the radioisotope on the body seems wrong.

If there is an opportunity to monitor infiltrations, then the data can be used for improvement. And while it may never completely prevent an extravasation, it will cause reduction-ultimately better for the patient-through feedback and/or training of the technologist. There have been several reports by clinics demonstrating this improvement from monitoring.

Reporting could be delayed while clinics improve their practices, if needed, so that the

concern with the work associated with filings would be minimal. To me, it seems very inappropriate to not want to improve, especially for the patients.'' Okay. That was from Susan Slane.

Okay. Kellee, let me check in. I'm going through the rest of these comments here. Kellee, let me check in to see if there's any raised hands.

MS. JAMERSON: Hi, Sarah. Yes, there are some raised hands. They may still be from the previous topic, and there are some that we didn't get to.

MS. LOPAS: Okay. That's fine. Yeah, just a reminder, folks. If you already raised your hand and you're done, you just have to click on that little hand to lower your hand so Kellee knows that you don't want to speak a second time. But if there's some that we didn't get from the last, Kellee, go ahead. And I'm going to start going to the top of my comments up here on the chat too. So I'll --

MS. JAMERSON: Okay.

MS. LOPAS: -- go to you next.

MS. JAMERSON: So next is Bryan Lemieux.

DR. LEMIEUX: Hi, thank you. I'm a medical health physicist with the University of

Kentucky. I wanted to comment on a couple things, sort of it fills in from the last series of questions but also into this series of questions.

So while I agree with many of the comments that have already been shared, there's a certain degree of reasonableness and logistics that NRC needs to consider in terms of licensee burden and also regulatory burden. Society of Nuclear Medicine and Molecular Imaging estimates there are roughly 20 million nuclear medicine procedures per year. If one considers a reasonable percentage or majority of those are by injection, then even if only one percent are extravasated, that's roughly 200,000 potential medical events per year that need to be assessed in some reasonable manner.

And the normal way that we have as we've already referred to for assessing whether or not there's sort of a substantial risk would be to do a dose-based estimate and say, hey, does this -- what can we screen out based on the dosimetry? And the problem with this is that the dosimetry from an infiltrated radiopharmaceutical is not really a trivial exercise, right? We have sort of an unknown volume of extravasate. We have a varying concentration of radioactive material into some sort

of interstitial tissue.

And even, like, for example, the references that you threw out before, the bonded paper for example, they've all taken different methods to try to estimate that dose. And really most of those are kind of a shot in the dark, right, because there's no good data on how quickly it was absorbed. There's not good data on the geometry. Okay.

And if we know these things, we have a way to do it. We can use MIRD, right? We can use voxel-based dosimetry if we want to dedicate the resources to multiple serial time point imaging which would be required to figure this out, right?

So I think NRC needs to consider on the tactical side, from the health physics side of it, there are true real logistical issues in this if we're using a dose-based sort of screening criteria because clearly there needs to be something, right, that has us not reporting every diagnostic technician extravasation. Should the position be reinstated that maybe we're looking only at patient injury or something like that, then that has to be addressed. In addition, a lot of licensees really don't have the resources to do these types of dose reconstructions, right?

There's still many licensees that might just have planar imaging. They might have onboard CT scanners. They may not be doing the CT or have an ultrasound available to try to visualize the volume over time. And the patient may or may not be compliant with all of this extra imaging and poking and prodding and things like that, right?

So these are real concerns on the licensee side for just sort of how to do the applied health physics evaluation for these things, right? And then, of course, there's a separate issue that goes into medical practice. And if we figure out what the dose is, and that's for our physician colleagues to determine, in terms of, like, how does that chance their care plan for the patient, right?

And is it meaningful if I calculate the dose to a radiopharmaceutical therapy extravasation has a Gray versus ten Gray versus six Gray versus two Gray? Is that going to meaningfully change the medical care and follow-up for that patient, right? I think these are appropriate questions to ask when we're considering the big picture as others have said in terms of how to address this issue. Thank you.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Okay. Kellee, do we have any other hands raised before I get to reading some of the chats?

MS. JAMERSON: Richard Wahl?

DR. WAHL: Yes, hi. I'm Richard Wahl. I'm a physician radiologist, nuclear medicine specialist. I'm president-elect of the Society of Nuclear Medicine, and I'm an elected member of the National Academy of Medicine.

I've had over four decades of experience in nuclear medicine and then the inventor of a couple of therapeutic nuclear medicine agents, radiopharmaceutical therapies, and have extensive experience. I think many of the points have been made. But I do think the overarching big picture concern is that of these regulatory requirements were put in place for what appears to be clearly as not as significant clinical issue that the patients who benefit from nuclear medicine, diagnostic and therapeutic, would stand potentially not to benefit because the cost of compliance would be immense and of little benefit.

So I think the benefit to patient could be easily lost, potential benefit, if there's not access to the technology. And some of the things

that have happened in nuclear medicine and medicine in general which operates on a thin margin or that COVID has reduced revenues in the medical centers by billions of dollars. They've estimated 60 billion.

Just in the last couple of days, CMS reduced payment for nuclear medicine and radiology procedures by about 10 percent. So this is a very thin margin business. So to add the regulatory cost without a clear benefit seems clearly harmful to patients that would strongly support the comments of the current regulatory structure as appropriate and it perfectly balances risk and benefit. Thank you.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Okay. Kellee, anybody else with their hand raised?

MS. JAMERSON: Pat Zanzonico, but I'm not sure if it's a second comment.

MS. LOPAS: Okay. Pat, do you have another comment?

DR. ZANZONICO: Yes, I have another comment. Thank you. Now I'm Pat Zanzonico, a nuclear medicine physicist from Memorial Sloan Kettering in New York City. And I'm also the chairman of the Medical Internal Radionuclide Dosimetry

Committee, the committee of the Society of Nuclear Medicine and Molecular Imaging.

And I think several of the points I was going to make were already articulated. But I did want to point out I think there's some insight we can gain from interventional radiology where skin doses are typically of the order of several Gray or hundreds of rads. And up to two Gray or 200 rads, there's no observable effects, either short or long term.

And even at skin doses up to five Gray or 500 rads, the skin effects are mild, transient, and self-limiting. And if you factor in the mitigating effect of the lower dose rates from an extravasated radiopharmaceutical, you can easily project that the significantly higher skin doses would have little to no clinical effect, as we already have heard. But the point is the quantitative data would substantiate that point.

The other point I want to make is that there are nuclear medicine procedures where radiopharmaceuticals are extravasated by design, mainly in sentinel lymph node biopsy procedures which are widely used in melanoma and breast cancer. And in those instances, there's no documentation at all of any adverse skin or other effects. So as so many

other speakers have said, so many other commenters have said, putting this in perspective not only is extravasation extremely, extremely infrequent but it's of little to no consequence.

And the final point I want to make and an earlier speaker did make this point is that estimating the radiation dose from an extravasated radiopharmaceutical is far from trivial. And without knowing how the earlier dose values cited were derived, I think that it's hard to say they were credible at all. And so for all these reasons, as many of the speakers have said, I really think there's very little basis for regulatory oversight and categorizing or recategorizing medical extravasations as medical events. Thank you.

MS. DIMMICK: Thank you for your comments.

MS. JAMERSON: Next, we have Josh Mailman.

MR. MAILMAN: Hi, I'm Josh Mailman. I'm a patient advocate and end user of all of these things. And I just wanted to echo a little bit of what Dr. Wahl said regarding what this would do to patient access and availability if as other commenters have said, there's 100,000 reportable

activities which would seem to be that there would be a lot more patient harm happening.

But if there were 100,000, how would people go through the data? What expense would add to patient care or patient availability? And then lastly if this did take away from patient availability because there would be some centers that would simple choose to do things that wouldn't require this level of reporting.

I do agree that it is important that if there is any harmful extravasation that occurs to a patient, that should be a reportable event as would anything that's harmful to a patient. But some of these things that we're discussing seem to be more in the training area to make sure that we don't have this challenge as opposed to that we're going to report everything that happens and maybe make this less available to patients. Thank you.

MS. DIMMICK: Thank you, Josh.

MS. LOPAS: Okay. If it's okay, Lisa, I'm going to take some time to catch up with some of these chat comments - so I'll read them aloud.

MS. DIMMICK: Okay.

MS. LOPAS: Okay. So the first one is from Jamie Eisenberg. And just to recap everybody,

some of these comments were back from previous slides. So this one talks about monitoring.

Jamie says, ''We do not monitor for extravasation, but because we have a documented process for patients needing a second dose, we know that we have about one a month. The number of injections is approximately 500 injections -- 550 injections a month. So they are not common.

Extravasation technology in the petition is still retrospective. Good technique is necessary. Majority of extravasations occur from inpatient IVs started on the floor that can vary in age. I do not believe that regulatory action is necessary.'' We have a comment from Kathleen Hintenlang, and she says she endorses Dr. Wallner's comments from the beginning of the meeting.

A comment from John Witkowski says, ''Thank you for the opportunity to comment, and I sent a written comment in during the petition public period. Under other factors and considerations, it is important to note that some of the images in the materials submitted to the NRC by the petitioner had high uptake of the radiopharmaceutical in the upper arm beyond the point of injection extravasation. It appears the uptake is that of lymphatic drainage.

Lymphatic uptake of the radiopharmaceutical would give rise to radiation absorbed dose beyond the point of injection to axillary lymph nodes. It appears that extravasation evaluation should consider dose to tissues beyond the point of injection, axillary lymph node. An alpha or beta emitting radiopharmaceutical might give high exposure to the lymph drainage.'' So that was a comment from John Witkowski.

This is a comment from Brian Goldstein. Brian says, ''Data has been submitted to the NRC that showed that extravasations are not rare. The monitoring that will improve techniques is feedback on these techniques. Finally, how can anyone assert that patients are not harmed when practitioners have not heretofore measured? Okay. And I think Josh spoke to this comment, John Mailman, when he just spoke now. But he said, ''Is this a training question or a practice of medicine issue; unless a certain threshold of activity is released or patient harm occurs?''

Jamie Eisenberg follows up on their comment saying, also, ''As nursing best practices are now being implemented into nuclear medicine departments, there has been a reduction of straight

sticking as an injection technique. The use of butterfly and IVs reduces the likelihood of extravasation. This further reduces the rate of extravasation over the last several years.''

Brian Goldstein continues with his comment, ''Absence of evidence is not evidence of absence. Apparently, some are saying that extravasations are not a problem and/or are not dangerous. The way to know whether this is true is to collect data, i.e., to measure and monitor. How else will we know?''

We have a comment from Michael Baxter who says, therapeutic quantities of radiopharmaceuticals can deliver doses that has -- oh, we already read this one. I apologize. This was the one that you addressed, Lisa, about how he was talking about how maybe extravasations are already captured under 3045. But they are not. So I did cover those two comments.

Another comment from Brian Goldstein is, ''Monitoring is a first requisite step to reducing the rate of extravasations if, in fact, they are occurring in ways that lead to radiation overexposure. No one is saying that monitoring alone is adequate. However, it is the only place to start.''

Okay. This is another commenter from -- I think we heard from Valerie. But Valerie, I'll go ahead and read your comment. So, from Valerie Jewells, ''I am the quality and safety officer at UNC. I agree with the previous comments by the nuclear medicine physician and technologist statements that there are very few extravasations and hence very little potential for untoward consequences from extravasation.

Therefore, monitoring is going to be overly burdensome for medical centers without a positive impact upon patient care. Hence, there's no need for monitoring and review of extravasations. There is also no definite method of prevention of extravasations beyond technologist education. CT scan extravasation is a very different situation due to the large dose of contrast that can result in compartment syndrome and skin sloughing. Thank you.''

We have a comment from Tricia Peters who says that she agrees with the SNMMI position that regulatory action is not required for radiopharmaceutical extravasation monitoring. Brian Goldstein says that, ''No one is talking about adjudicating the quality of scan. The need is to

measure for radiation exposure.'' So that, I think, was in response to, I think, Dr. Schleipman's comments.

Let's see. Angie Morgan Hill, she notes that -- she agrees that ''Monitoring should not be required by regulators such as myself. Monitoring may be a corrective action post-medical event.''

Rochelle Batdorf says, I find it interesting that other types of extravasations, such as those with Chemotherapy, cannot be monitored or always prevented. It is interesting that regulators would be concerned regarding radiopharmaceuticals because we can detect these with imaging. Angie Hill says that a licensee will know if they had an extravasated dose or not.

Let's see. Rochelle Batdorf follows up that she still finds it interesting that we'd be concerned about radiopharmaceuticals detecting these because they can be detected with imaging. And she goes on to note, especially since an extravasation with chemo could result in a medical issue.

And Carmine Plott notes, ''While no technology exists to prevent extravasations, we rarely have extravasations because we utilize catheters, such as Angiocaths, to establish IV access

rather than performing direct sticks.'' And David Williams poses this question, ''We are being told the events are common and the events are rare. Which is true?'' So I don't know, Lisa. I don't know if we want to address that at all.

MS. DIMMICK: So the statistics, 0.1 to 16 percent. So extravasation can happen. But an effect that causes harm to the patient where there might be medical follow-up, that is what is rare. That's what we're seeing in the literature reviews. So while there might be an occurrence on the upward to 15 percent, the observable effects requiring patient -- I mean, follow-up with a physician, that's what is seen as rare by the literature studies.

MS. LOPAS: Okay. Thanks, Lisa.

MS. DIMMICK: Okay.

MS. LOPAS: David Bushnell comments, ''Greetings, I am a national VA Program Nuclear Medicine Rad Safety Director and I am deeply concerned that any effort to regulate extravasation would place an undue burden on VA nuclear medicine and RSO staff throughout the nation without any clinical care benefit to be gained. Okay. Andrew Zimnoch says, ''Is IV administration into the patient's arm the only route of administration being considered? A central

line or a PICC line can also be used.'' So that's a note about the type of administration. Let's see. Dr. Paul Wallner also says -- and I have to kind of remember what this is in reference to.

MS. DIMMICK: Let me read the comment, and let me just comment because I probably wasn't clear on what I was trying to get at. So, Paul Wallner notes, ''No distinction should be made. The rare occurrence of this event makes policy changes unnecessary. Yttrium-90 microspheres are typically administered through catheters directly into the liver where extravasation is not a real issue.''

My reference to the yttrium-90 was that in the medical event reporting criteria for microspheres, there's a caveat with regarding to shunting. So, I wasn't saying that yttrium-90 events -- we're not equating that to anything with extravasation. I was just saying that with the medical event reporting criteria for yttrium-90 microspheres, there is a caveat for shunting.

And so the thought was, is there something that should be a caveat with regard to extravasation, not yttrium-90, but with other radiopharmaceutical administrations and extravasation. Just thinking in terms of what

criteria might be set for extravasations if we were to move in that direction. Okay.

MS. LOPAS: Okay. The next comment, I think this is a clarifying question about the petition, Lisa. And I'll repost the link to the petition docket so folks can read the petition for rulemaking. But I think they're asking here -- Michael Bellamy is asking in reference to the 50 rem dose equivalent. ''Is this referring to skin dose? If so, is the dose averaged over the entire skin mass?'' Lisa, I'm not sure if you recall from the petition, what the exact wording is on that.

MS. DIMMICK: I think the petition just uses a 50 rem localized dose and isn't explicit to skin. I think it just is referring to a localized dose of 50 rem and it's just that.

MS. LOPAS: Yes, and I will repost the regs.gov link. And you all can pull up that petition and read in detail more. Just give me a moment on that. Dr. Wallner notes, ''One problem with the dose-based definition is the nature of extravasation itself. Every patient has a different habitus, different rate of diffusion, different volume extravasate, different agent, and different activity.'' Okay.

And Michael Hall notes, ''For therapeutic administrations requiring a written directive under 10 CFR 35.300 or 10 CFR 35.1000, we agree that extravasations may cause unintended permanent damage. The regulations call for treating such instances as medical events, which reasonably covers the rationale for the petition. In addition, greater care is taken for these administrations, and intravenous patency is often verified by either diagnostic radionuclide injection or blood return, but such events may happen regardless.

The outcome of such events would depend on the activity deposited at the injection site and the removal rate, which cannot be predicted.'' Okay. Kendall Berry follows up with, ''Dose estimates are largely hand waving and theoretical. We can use a variety of assumptions to guestimate a dose, but ultimately the skin will be the dosimeter. But results may not be fully appreciated until months later.'' Okay.

Angie Hall is noting, I think, from our 35.3045 medical reporting regulations. ''It would be a dose to an organ (extravasation).'' So I think she's just pointing out what part of the regs maybe these would be theoretically reported under. Matthew

Williams says, ''Dose estimation would have to be done using some Monte Carlo-based software. Assuming it as a point source at the site wouldn't be a safe assumption as it will release will some biological half-life into the blood stream and evacuated.''

Miguel de la Guardia says, ''There is no additional risk from extravasations of radiopharmaceuticals as from gadolinium or iodinated contrast media. This is just another regulation to track a very rare event that might cause injury. Administration of therapeutic radiopharmaceuticals is very safe as proven by the sparsity of reported events in literature or elsewhere.'' Okay.

And I have a comment from David Crowley from the State of North Carolina and who's the current chair of the Organization of Agreement States, the chair of their Executive Board. David says that, ''Especially for therapies, i.e., treatments of written directives,'' he says, ''Many Agreement State programs do consider extravasations to require reporting should they meet the current medical event reporting criteria. NRC, however, exempts all extravasations at this time, including therapy.''

He's sharing that and he's encouraging licensees to reach out to their Agreement State

regulators to understand the expectations in their cases. So that's a note from David Crowley on behalf of the Agreement States. And another comment here from David Switzer.

''The U.S. NRC has a protocol for establishment of approved procedures which includes medical appropriateness, efficacy, and safety. In every medical procedure, there are risks. The patient's physician is responsible for the explanation of the pertinent risks and benefits. The patient accepts or not. The comparison most likely has been made to extravasations in non-radioactive cases.''

Okay. And we're almost towards the bottom of these. We're getting there. Lisa, let's do a time check, 3:47.

MS. DIMMICK: Let's do the last two slides --

MS. LOPAS: Okay.

MS. DIMMICK: -- and then we'll finish up with these comments. So go ahead, Kellee. Next slide, please. So some of these things, we've already discussed or you maybe have pointed out in your comments. But other factors that should be considered with regard to extravasation, obviously

patients themselves are the factor based on their age, anatomy, physical condition, and whether or not they've had prior medical treatments.

The radiopharmaceuticals, it's the dose being administered and the volume of the radiopharmaceutical. Also, the radionuclide and energy emissions, the injection rate, is this a bolus injection or a slow infusion? And also, the formulation of the radiopharmaceutical, what might that contribute to the irritation or as the vesicant?

Dose delivery, looking at the type of vascular access device, location of the chosen vessel. Are these hand injections or is this some sort of power injection? And then skill of the person placing the vascular access. Next slide, Kellee. Because any thoughts that you might have on these topics, please share.

And in our research and discussions, we've come up with -- we've heard of another term that might somehow imply leakage or extravasation or infiltration of the radiopharmaceutical or drug diffusing out versus extravasate. Is there really a difference here? If there is, I'd be interested to know what that is.

And then are there any injection quality

initiatives underway that people are participating in just to improve injection quality? And then, if possible, just how often are scans repeated due to radiopharmaceutical infiltration or extravasation? We did have a couple of comments on that very topic.

So if anyone has anything else, that would be great. And then anything else that you think the NRC should be aware of or think about as it continues its evaluation of extravasation. So, with that, we'll continue with comments and reading them and any comments that people want to give over the phone.

MS. LOPAS: Kellee, I see we have a couple hands. Do we want to start with the hands raised?

MS. JAMERSON: Sure. First is David Schuster.

DR. SCHUSTER: This is David Schuster. I am the Division Director of Nuclear Medicine and Molecular Imaging at Emory University in Atlanta. I've already given written comments, so I'll be brief.

I believe the current framework is fine. I think that the times that we do repeat a scan due to radiopharmaceutical infiltration extravasation is pretty uncommon. And as other experts including a

medical physicist noted, it was practically impossible to implement a specific threshold for reporting. But I would like to address some comments in the slide as well and from others that this regulation is the only manner to improve practice.

We know when a significant extravasation occurs by monitoring the images which we do as nuclear medicine physicians and radiologists and patient outcomes which does trigger QC-QI actions already in place. We already implement this ongoing QC monitoring and address them as part of the practice of medicine where I believe this issue belongs. And also, I have to say that this petition in my opinion is an attempt to use regulation to encourage sales. Thank you.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Okay. Kellee, next hand raised?

MS. JAMERSON: Next is Ralph Lieto.

DR. LIETO: Yes, I want to thank you for the opportunity to comment. I have a couple of comments that I would like to make and one is I want to -- the other factors and your considerations that you have indicated here, I think to the points that

were very well made by Pat Zanzonico and Bryan Lemieux on the issues of dosimetry. And I want to echo also that their comments about the difficulty, the logistics that go into doing any type of a dosimetry regardless of what threshold is being determined is not something that is logistically achievable by most nuclear medicine facilities, especially those in the community setting where they do not have medical physics availability to perform these types of very lengthy and involved calculations.

Another comment I wanted to make about the extravasations, if they were made medical events, is that this is not a process improvement mechanism which is alluded to by some of the people supporting this petition. If anybody has been involved with reporting a medical event, and I have been on at least three occasion, been involved in this process and in investigations and one of which achieved some national notoriety. These are very difficult things to go through.

It requires immediate reporting within 24 hours into a public process. So immediately when this is reported, the licensee is documented into a public record that is viewable by anybody that monitories that bulletin board, if you will, of the

NRC that a medical event has occurred and the general nature of it. And that usually, if the NRC is doing their snuff, triggers an onsite investigation.

So a medical event is not a process improvement mechanism. The other thing about medical event reporting of extravasations, this would be really unprecedented in terms of how extravasations are reported. Nowhere else are non-radioactivity extravasations reported to any state or federal agency.

They're handled as an internal process improvement and medical error event that is handled usually by the internal processes of their respective licensee. So I think that is something that needs to be considered in this petition. And I wanted to also make a comment on something that the NRC staff has mentioned regarding the 1980 position and statements on extravasations and that maybe this needs to be reevaluated because the practice and how nuclear medicine is down now in present day differs significantly from the way administrations in nuclear medicine in 1980 was done.

I would say probably that would be true in the case of the types of radiopharmaceuticals that are being used. The state of pharmaceuticals back

then delivered much higher organ doses and were not pharmaceuticals that are used now currently for common imaging such as kidney imaging. The common imaging back then was I-131 Hippuran.

But I will say the one thing that has not changed and I'm speaking from experience of being a clinical nuclear medicine physicist that practice back at that time period that IV sticks have not changed really in any significant manner from 1980 to 2020. So I think that how these radiopharmaceuticals are administered is not significantly changed except I would say in the manner of which the therapy administrations have improved significantly in their way of administration. I think that this petition and the fact that the 1980 position should again be -- shall I say re-upheld is something that I hope that the NRC will do. Thank you.

MS. LOPAS: Thank you. All right. I am going to read through some of these chat comments, and then we'll check back in with Kellee quickly. From Matthew Williams, ''I think there's a false equivalency that reporting to the NRC would reduce the number of extravasations. Many speakers have pointed out that the vast majority of these extravasations are out of the hands of the

technologist or MD.''

From Kendall Berry, she notes that, ''The licensee burden would be explaining again that the problem is that IV extravasations unfortunately happen for a variety of reasons and there may be absolutely no corrective actions that can be taken. That would be a significant burden on licensees. It has been clearly covered in this discussion that we would simply be rehashing known and documented information with inspectors with no benefit to the patient.''

I had a comment from William George who says, ''I work for Lucerno Dynamics, the petitioner, and wish to correct an inaccurate statement by Dr. Jewells in her verbal comment. We did not ask UNC, nor any other customer, to collect patient names, date of birth, or other Protected Health Information as defined in HIPAA. Centers using our product may enter medical record numbers into our software as a patient identifier, but whatever is entered to this field is deidentified using one-way encryption as specified by NIST. Dr. Jewells' insinuation that Lucerno collects PHI in order to sell it is categorically false.''

From Deirdre Elder, Deirdre says, ''It is

very difficult to determine why an extravasation occurred, whether of contrast media or radiopharmaceuticals. Some patients have weaker blood vessels and are more likely to have an extravasation. Also, estimating the tissue dose would be very difficult. I don't support an NRC regulatory change to make extravasations a reportable medical event. However, if NRC requires extravasations to be recorded as medical events, the NRC needs to provide guidance on methods to calculate the skin dose.''

Dr. Wallner says, ''Almost anything can be monitored. In this day and age, the overriding question is value? There is insignificant clinical value to monitoring proposed by the petitioner.'' And Tina Buehner says, ''Best practices for administrations of intravenous injections through IV catheters.

We, as a medical community, need to communicate and stress the importance of IV injections which significantly reduce the chance of extravasations.'' Dr. Jadvar -- Hossein Jadvar states that, ''The range of infiltration of 16 percent seems to be taken from a JNMT paper published in December 2019 with the Lucerno company reps as

authors. The meta analysis from EJNMMI publication in 2017, the rate of extravasation is substantially lower at less than one percent.''

Jeremy Iman says, ''If the concern is 50 rem, which radiopharmaceuticals could even cause this? Is Lutetium-177 the only one? The way it's administered is via a catheter where blood flow is checked and continuous saline is being flushed. Reporting extravasations that could exceed 50 rem seems to be a very minuscule portion of nuclear medicine radiopharmaceuticals on the market.''

And Angie Hill notes that -- Angie Morgan Hill notes that, ''Yes, extravasations are clearly visible to the eye of the licensee. It can also be seen on gamma camera.'' OK, I think we're getting close to the end, and I want to check in with Kellee to see if there are any other hands raised. And then I have a -- Valerie, if you want to type me a statement, I can read it aloud or you could also potentially speak aloud. But Kellee, let me know if there's any other hands raised.

MS. JAMERSON: First, we have Tina Buehner.

DR. BUEHNER: Hi. Yes, Tina Buehner, health physicist, Rush University Medical Center and

president of the SNMMI-TS. I just wanted to address the question on quality initiatives underway. Just to reiterate, from the technologist section, we are addressing this.

And we do know that best practices for administration of radiopharmaceuticals are to administer them through these catheters, and this isn't always happening. When they are administered the catheters, this significantly reduces the chance of these extravasations. And we need to communicate that.

So we're wanting to do that, communicate this to our members. And it starts with the authorized users and the manager and implementing protocols in their department that require that they have catheters in place. Straight sticking is not something that is recommended anymore. So this is part of our initiative. And like I said before, we're going to be addressing it from the quality and the impact it has in our recent study.''

MS. LOPAS: Okay. Thank you, Tina. All right. It's 4:01. We're going to do last call for comments. So if your hand is raised now, we'll get to you. But then we'll probably close out after that. So Kellee, let's go to our next raised hand.

MS. JAMERSON: Next is Drew Garner.

MR. GARNER: I'm a 65-year-old cardiology patient from Atlanta, Georgia, and I recently had one of these procedures. And first, I'd like to address the physicians who suggest that it's a patient's fault in any shape or form. We're guinea pigs sitting on those tables, and it's also an insult to my 4-year-old granddaughter who's a very brave patient. So I just really just can't handle that comment.

But let me talk about a document I read as one of the comments to the NRC. It was the Organization of Agreement States. There's about 40 states represented there. I believe that is the most comprehensive, credible, fact-based, patient-centric opinion that could be written on this subject.

My technician was more concerned about getting a date, talking to his fellow technician in the next cubicle. I just don't know how good that was, but it scares the heck out of me. And the more I've learned about this quite by accident it concerns me.

So I certainly suggest everyone on this call read what the OAS reported. I believe Dr. Wong suggested there's around 15 percent extravasation rate, and that's a lot. Out of 100 patients, 15. I

don't care if it's one percent. I don't want to be that one patient.

So I would just urge everyone to think about the patient. I haven't heard anything from patients on this call, but I'm concerned about it. I also read in this same article that -- this opinion that you can spill a dose of this stuff on your skin and have to report it. But if you mis-inject it, you don't have to report it. And that alone just seems odd to me and very concerning. So just as a patient, I would tell you this is so critical for us.

And yes, did I light up my congressman, Congresswoman McBath and Senator David Perdue? You better believe I did. When I found out more and more about this and did my own research, this is an issue and it's just getting bigger and bigger. So to minimize it is not appropriate. So I'm glad I had an opportunity to participate and thank you for this opportunity.

MS. DIMMICK: Thank you for your comments.

MS. LOPAS: Kellee, it doesn't look like we have anymore hands raised. Is that correct?

MS. JAMERSON: That's correct. I'm showing no new hands.

MS. LOPAS: Before I hand it over to Lisa to close out, I just want to remind folks that we will do a meeting summary of this meeting. There will be a transcript that'll be publicly available. And we'll get those posted on our medical licensee toolkit, and we'll get the email out via our medical list server.

So if you hang on to the WebEx, I'll put those into the chat again before I close out of here of the WebEx so you can have those email -- or those links to get to. So you can get our list server if you're not on it and you can find our medical licensee toolkit as well. So with that, I will hand it over to Lisa.

MS. DIMMICK: Okay. Just a couple of things. Thank you everyone for your support and participation today. All comments were very valuable and beneficial to NRC staff as we continue to evaluate extravasation from all angles, sides, what have you. So we really appreciate the comments and the insights that you offered. And we will carefully review everything that we received as we continue to move forward.

So just typically anything about extravasation that becomes publicly available, we

will continue to communicate that via our medical listserv. And as things progress, I'm certain we'll keep the public informed. So again, thank you and have a great day.

(Whereupon, the above-entitled matter went off the record at 4:06 p.m.)